STUDY PROTOCOL
aDolescents gEnder surVey, rEsponsible coupLes evaluatiOn, and capacity building Project in India (DEVELOP): a study protocol [version 1; peer review: 1 approved with reservations]

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Abstract
Gender-based violence against women is a serious concern in India. This affects the health and wellbeing of victims and their dependents. Published evidence has documented a variety of reasons for such violence in Indian societies, paving a pathway to design, implement, and evaluate intervention models to address this issue. DEVELOP is a research study designed by UK and Indian research teams to plan future projects to address gender-based discrimination and violence against women and girls in India. This study protocol provides detailed information on the objectives, research methods, data collection, storage, analysis, and dissemination plans of the DEVELOP. The first component is a survey of adolescent boys and girls from rural areas of Maharashtra state of India to understand their gender equality related knowledge and beliefs. The insight gathered will be used to design interventions targeted at adolescent populations through future research and development programmes. Secondly, an evaluation of the 'Responsible Couples' project will be conducted to assess its success and challenges, and to design suitable programme activities and models. The 'Responsible Couples' project is implemented in 40 villages of Maharashtra state to improve relationships in married couples, prevent violence against women, intervene during violence, and to provide support services for women and their family members. Research findings will be disseminated though public engagement events in India, international conferences, and peer reviewed publications. This will impact on the policy and work models of Indian partners to plan future project investments. Research findings will be also useful for local government authorities and non-government agencies striving to advance gender equality.
Keywords
Gender, Maharashtra, India, Adolescent, Violence, Evaluation

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Competing interests: DEVELOP project has an evaluation research component (section II. Qualitative component) focusing on the on-going gender equality programme, which is funded by the SWISSAID. SWISSAID is a lead partner in India to support DEVELOP research activities. Ms Sneha Giridhari, who is involved in this project and also one of the authors, is currently employed by the SWISSAID as a programme officer and is involved in monitoring the DEVELOP project progress.

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The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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Introduction

Gender-based violence against women is a fundamental violation of women’s human rights, health, and wellbeing. Globally, intimate partner violence (IPV) is the most common form of gender-based violence against women. A recent study from south India reported that over 50% of women had experienced physical domestic violence ever, and 27% faced physical domestic violence in the past six months. The majority of female victims are married to the perpetrator and underreporting of IPV is a known phenomenon. IPV is linked to a range of factors including alcohol addiction, financial debt, cultural and social acceptance of violence, and childhood trauma/exposure to violence. These factors are also linked to gender-based discrimination, adversely affecting girls and women’s health and well-being, their ability to continue their education, choose a career, make informed reproductive decisions, and achieve financial independence. Adverse effects of gender-based discrimination on girls’ and women’s health and wellbeing are particularly high in deprived communities.

Although the need to reduce gender-based violence and empower women in India is widely recognised, there is very limited information available on gender equality-related knowledge, attitudes, and behaviours among Indian adolescents, who are an important age group to target with public health and development interventions. Moreover, traditionally, interventions to reduce gender-based violence and empower women were focused on women, and men were predominantly left out of such interventions. Overall, there is very limited research on the effectiveness of gender-based violence reduction interventions.

With financial and technical support from the SWISSAID, Halo Medical Foundation (HMF), an NGO working in Maharashtra state of India, has developed and is currently implementing the ‘Responsible Couples’ intervention to address gender-based violence against women by educating men, supporting women, and providing village infrastructural facilities to create healthy relationships and violence-free communities. The ‘DEVELOP’ project seeks to increase understanding of gender equality-related knowledge, attitudes, and behaviours among Indian adolescents, as well as evaluate the ‘Responsible Couples’ intervention. The project is planned to be conducted in Maharashtra state of India in 2019. This paper is a study protocol of the DEVELOP providing detailed information on study objectives, research methods of two main components of the project, data storage, handling, and dissemination plans.

Protocol

Project goal

To conduct feasibility and capacity building work in India to support future research and development projects in gender equality.

Research objectives

- To inform the development of a survey tool measuring gender equality related knowledge, attitudes, and behaviours in Indian adolescents.
- To conduct a qualitative evaluation of the current gender-based violence reduction intervention—the ‘Responsible Couples’ project in the rural region of Maharashtra state of India.

Study design

This study has two components as outlined below to achieve the research objectives. The project team structure and partners are outlined in Figure 1.

I. Quantitative component - a questionnaire survey of the gender equality beliefs and attitudes of minimum 1000 young people (male and female) aged 16 to 19 from 70 villages of Maharashtra state, India.

II. Qualitative component - focus group discussions with the local gender equality promotion groups in 12 villages of Maharashtra state to explore their views on the implementation of the ‘Responsible Couples’ project, what challenges they are experiencing in their gender equality work, what they feel about the impact of their work, and how the project can be improved further.

I. Quantitative component

Selection and recruitment

The project field consists of 70 villages from HMF’s area of work, located in Osmanabad district of Maharashtra state of India. The study will invite all adolescents aged 16 to 19 from 70 villages to participate in the project by completing a questionnaire. These villages define HMF’s current geographic scope based on funding allocated by the SWISSAID to work in Maharashtra. Future programme and intervention development work will involve the same villages; therefore, these were considered in the DEVELOP research project.

Each village has a member of HMF staff linked to it. This individual will help distribute written information about the project (in the form of a leaflet, Supplementary File 1) in each village at least two weeks before any data is collected. Leaflets will be distributed to cover all community areas in each village. There are also field staff such as healthcare workers in project area. These workers are also able to provide any verbal description of the project if required at this point in time. They will also orally inform of the date of the data collection event. All staff members including field staff received necessary research and ethics training in February and April 2019 and are supervised by a senior research co-ordinator on a daily basis with additional support from a project manager based at HMF.

Data collectors will then visit the village for one day of data collection. They will set up their station at a village health centre, school or other locally available building/resource, where interested adolescents will be invited to visit to find out more about the project. Written and verbal explanations will be given to those who have not seen the previous information sheet (Supplementary 1).

The study will be open to boys and girls aged 16 to 19 only. Participants should be able to read and write in local language (Marathi) in order to understand the project information sheet and complete the data collection form independently. Data collection documents
were translated from English to Marathi by a project manager in the first instance, and the translation was verified by authors with bilingual proficiency (AA and SG). The final data files were reviewed several times to ensure its accuracy. The adolescents who agree to participate will be given a questionnaire, pen, and sealable envelope. The on-site data collection staff will address any queries, if asked by participants.

**Sample size**

The adolescent survey will be conducted to collect a minimum of 1000 questionnaires. This number is based on discussions with project partners to ensure that results from this study will be applicable to rural areas of Maharashtra state. This is also the maximum number of participants this project could achieve considering available resources. A similar
strategy was used to conduct research in this field area involving adolescent girls.

In order to collect representative data by age and gender, a stratified sampling technique will be used. In total, a minimum 1000 questionnaires will be completed, including 125 from each age group and 500 from each gender. This is the ideal sample scenario; however, no participants will be turned away on a data collection day even if the said number has already been achieved.

Survey instrument
A survey questionnaire in the local language (Marathi) will be used to collect data from adolescents. An English version of the questionnaire is available as Extended data. The tool is developed based on a validated and published questionnaire, which was used to study gender equality among Indian adolescents. The questionnaire was iteratively revised and improved within the team, discussed with partners, and then piloted and validated prior to administration. The outlined process was completed through focus group discussions and a testing phase involving adolescent boys and girls at the HMF training centre in March 2019. The feedback from the discussions was included, and minor changes were made mainly on the structure of the data collection form. No major changes such as question re-structuring were required. The questionnaire used in this study has a section on basic demographics (12 questions) and three individual sections to measure knowledge (nine statements), attitudes (six statements) and behaviours (seven statements) related to gender equality.

Data collection, analysis and storage
To ensure confidentiality, questionnaires will be completed in an area of the village hall/health centre that affords privacy. The completed questionnaires (in sealed envelopes) are then placed in a box by participants as they leave the hall/data collection centre. The overall data collection will be supervised by a qualified member of HMF staff.

The questionnaire will not collect any personal identifiable information such as name, home address, or contact details. Both the study information sheet and the questionnaire will include information assuring the participants of confidentiality and how the data will be used. Participants will not be identified or identifiable through reports or publications and only the research team will have access to the data. All data in India will be stored on a password-protected computers and encrypted USB devices and will only be accessible to the project and research teams. The survey data will be moved to the University of Hull, UK in a Microsoft Excel file, stored on a secure server and used for analysis purposes. A member of the research team will access the data stored at HMF office in person and will upload the data remotely to the University of Hull online storage server using secured login details. This will be verified by another team member to ensure that all data are safely moved to the University of Hull online storage system. The data will be stored for five years following the project completion.

Incomplete questionnaires will be discarded from analysis and stored for auditing purposes. Survey responses will be analysed in Stata (StataCorp, College Station, Texas, USA) and/or SPSS (IBM) using descriptive statistics, tests of statistical significance, and reliability coefficients. If data permits, then additional analysis to compare results across villages/blocks/districts would be also conducted. Results will be reported in line with STROBE guidelines.

II. Qualitative component
Selection and recruitment
The ‘Responsible Couples’ project is currently being implemented in 40 villages of Osmanabad district of Maharashtra state, India. Each village has one local group comprised of 15 to 20 village members, who are working towards gender equality in their community. Group members have been trained by subject experts and receive mentoring support from HMF project implementation staff. The groups provide support and facilitate access to victims of IPV and intervene to prevent violence against women, focussing on those who are married and living with their husband and/or in-laws. Importantly, as part of HMF’s work to support research development, these groups have been involved in the inception of the current research study.

From a list of 40 villages, 12 villages will be randomly selected for focus group discussions. In order to ensure random selection, all villages will be randomly numbered by a project manager based in India, and a total of 12 numbers will be selected by a member of the research team (AA, based in the UK). The process will be completed over email to record the process. At least two weeks before focus group discussions are held, members of the research/project team will convene meetings with the members of the village gender equality groups in the selected villages to describe the project and answer questions. To accompany the verbal description of the project, each group member will receive an information sheet. Only existing members of the village gender equality groups in the selected villages will be invited to participate in focus group discussions.

Sample size
Twelve focus group discussions are expected to provide sufficient insights into the implementation of the ‘Responsible Couples’ intervention across 40 participating villages. It is expected that up to 10 members from each village will participate in each focus group discussion. Based on our series of consultations with partners, field visits, interactions with beneficiaries, the proposed 12 focus group discussions is expected to be sufficient to achieve data saturation.
Focus group discussion instrument
A discussion guide in a local language (Marathi) will be used to facilitate focus group discussions. An English version is included as Extended data (Supplementary 4). Data collection documents were translated from English to Marathi by a project manager at first instance and were verified by authors with bilingual proficiency (AA and SG). The final data files were reviewed several times to ensure its accuracy. The discussion guide was revised iteratively within the team, discussed with partners, and then piloted prior to research use. The interview guide was used to conduct discussions in two villages from the project areas where its structure, questions were tested. This was attended by a project manager and a senior research co-ordinator to provide feedback to investigators based in India and the UK. No amendments to the guide were required.

Data collection, analysis and storage
Focus group discussions will be conducted, transcribed, and translated by two experienced facilitators with bilingual skills (Marathi and English) under the supervision of the research team. The qualitative data will include information on the views of village level groups on: the implementation of the ‘Responsible Couples’ project; what challenges they are experiencing in their gender equality work; what they feel about the impact of their work; and how the project can be improved further.

No personal information will be collected during the focus groups. The information sheet will include assurances on confidentiality and that no identifiable data will be used in reports and publications. Only the research team will have access to the data. All data in India will be stored on password-protected computers and encrypted USB devices and will only be accessible to the research team. Once research activities are completed in India, the focus group discussion data will be moved to the University of Hull, UK in Microsoft Word and PDF files with the audio recorded discussion files, stored on a secure server and used for analysis purposes, as described for the quantitative data.

Qualitative data from the focus group discussions will be analysed thematically and organised in NVivo (QSR International). Two researchers will independently code data and synthesise the findings into themes. They will then meet to discuss areas of agreement and disagreement and reach consensus on the coding tree, illustrative quotations, and interpretation. Results will be reported in line with COREQ guidelines.[12]

Ethical statement
The study has been approved by the Faculty of Health Sciences Ethics Committee, University of Hull, UK (approval reference number- FHS125 issued on 3rd April 2019) and the ethics committee of the Ashwini Rural Medical College, Hospital and Research Centre, Solapur, Maharashtra, India (approval reference number- ARMCH/IECHR/03/2019 issued on 15th March 2019).
All survey participants will give individual oral informed consent before completing the questionnaire. The oral informed consent was preferred in this survey to ensure full confidentiality of participating adolescents. Written consent requires basic details such as name, address with further requirements of anonymisation. These details are not requested on the questionnaire and therefore oral informed consent is deemed sufficient from a willing participant before handling over the questionnaire. As a result of this, no personal information on participating adolescents such as name or address are collected at any point of time. All focus group participants will give a collective written informed consent before participating in focus group discussions. This strategy was decided following consultation with our project partners. At the start of the session, a collective signed consent form will be obtained. In India, the provision of a personal signature on a form is regarded with some suspicion and the collective form alleviates this. Further, all eligible participants are active members of the village level group and regularly meet for monthly meeting and thus are aware about collective signatures as a part of on-going project activities. This also allows the data collection team to collect the signatures of willing participants where individual names, addresses and contact details were not collected. The consent form is provided as Extended data (Supplementary 5).

Dissemination of information
The results of the study will be disseminated via local, regional, and national dissemination events, online video and blogs, peer-reviewed publications, and presentations at international conferences.

Study status
The DEVELOP project duration is from December 2018 to July 2019. The study is currently in the data collection phase (planned to take place from April to July 2019).

Conclusions
To the best of our knowledge, this will be the first survey from the Maharashtra state of India, and one of the largest surveys, measuring gender equality-related knowledge, attitudes, and behaviours among Indian adolescents. The survey findings will generate new valuable insights into how adolescent groups could be engaged in the future to improve gender equality in Indian communities.

The qualitative evaluation will inform the implementation of the ‘Responsible Couples’ intervention and strategies to improve it. It will also have policy implications for HMF, SWISSAID, and other organisations seeking to reduce gender-based violence and empower girls and women in Maharashtra and other states of India. Considering diverse Indian culture, practices, and beliefs, the study results may not be completely generalizable beyond the population studied.

The DEVELOP project will contribute to research capacity building and evidence-based practice in a limited resource setting. The project will provide opportunities to train and engage over 10 researchers and practitioners in Maharashtra state of India to improve their knowledge, develop new research skills, and enhance their experience of collaborating with international partners. It is expected that the project will help partners involved from India and the UK to develop further research on the adoption, implementation, and scale-up of evidence-based gender equality
interventions in Maharashtra and other Indian states and territories.

Data availability
Underlying data
No underlying data are associated with this article.

Extended data

This project contains the following extended data:
- Supplementary Files 1 to 5.pdf (participant information sheet for questionnaire, questionnaire in English, participant information sheet for focus group discussion, focus group discussion guide in English, focus group discussion consent form)
- DEVELOP_Survey questionnaire Marathi.pdf (questionnaire in Marathi)
- DEVELOP_FGD Guide Marathi.pdf (focus group discussion guide in Marathi)

Data are available under the terms of the Creative Commons Zero “No rights reserved” data waiver (CC0 1.0 Public domain dedication).

References


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Grant information
The DEVELOP project is formulated following a travel grant awarded to Prof Mark Hayter and Dr Anand Ahankari in May 2018 from the Global Challenges Research Fund (GCRF) allocated to the University of Hull, UK. The project received a dedicated grant in November 2018 from the Global Challenges Research Fund (GCRF) allocated to the University of Hull, UK. Dr Pavel Ovseiko is supported by the European Union’s Horizon 2020 research and innovation programme award STARBIOS2 [709517] and by the National Institute for Health Research, grant NIHR Oxford Biomedical Research Centre [BRC-1215-20008] to the Oxford University Hospitals NHS Foundation Trust and the University of Oxford.

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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Open Peer Review

The paper is a study protocol of research proposed in Osmanabad district of Maharashtra, India to improve evidence-base for understanding and acting upon gender-based violence (GBV). The study seeks to understand gender equality related knowledge, attitudes and practices among adolescents on one hand, and evaluate an ongoing intervention to reduce gender-based violence, called “Responsible Couples” (RC). The authors make a strong case for the need for such evidence (from adolescents, where interventions targeting the problem ought to begin) as well as the relative lack of effectiveness evidence from interventions to reduce GBV. Authors indicate that this could be the first of its kind large survey on this topic in Maharashtra, and perhaps among Indian adolescents. In addition, their remarks on the research capacity-building and academic exchange involved are also noted with appreciation.

Background
The background provides a published estimate of domestic violence (DV) ever and DV in the past 6 months. The study cited surveyed households in one city of south India, whereas the background states this as being an estimate for south India, which may not be an appropriate representation of the original study’s findings.

Improving coherence through more contextual information and clarifying objectives
A project goal is separately provided in addition to the research objectives. The two research objectives focus on (1) survey tool development for adolescents, and (2) evaluation of the RC program. The project goal is quite broad and both objectives fit within this goal, but it is unclear how these two objectives come together. Is there any specific reason these two objectives have been chosen? What was the rationale for choosing this particular intervention? Perhaps this is related to specific contextual information that may not be part of the protocol. Researchers could consider a section that describes the particular setting where the study is being planned as well as perhaps a section that describes work leading up to the study to provide the reader an understanding of the logic/reasoning in choosing these two objectives in order to work towards the project goal.

While the background indicates that the authors will undertake a survey among adolescents (and indeed the data collection and subsequent activities confirm this, the first of the two objectives that include this...
appears to stop short at “…inform(ing) the development of a survey tool”. This gives an impression of this being a tool-development/feasibility study only. Clarify.

**Selection and recruitment**

- The project identifies 70 villages which correspond to the area of work of partner NGO as being the study area. It is unclear from the information provided how much of the district this covers, and what the original logic is for the partner NGO to choose these villages. Since a survey is being planned, the reporting of its findings will depend on the overall choice of study site and sampling and hence further information has to be provided to enable an understanding of the study area. Some information on the larger context in terms of how this district compares with other districts in the state with respect to GBV are useful (if available). An estimate of what proportion of the district is covered by these villages is also useful.

- Authors indicate that the age of eligible respondents for the survey shall be 16 to 19. How will this be verified (if at all)? Will this be based on self-reporting of age? Or will researchers have an estimate/list from prior work?

- Will estimates/identity of adolescents in these villages be available to researchers from the existing work of partner NGO? If yes, specify how this data will be dealt with and used/not used. Authors may consider comparing their village-wise sample with adolescents in the village to come up with an estimate of their overall survey coverage among adolescents.

- If adolescents who are unable to read/write turn up, what will the team do? There are both technical and ethical implications of this decision to exclude this group, even if the numbers in this group are small. More so given that educational status has been declared in the background to influence GBV.

**Sample size**

- Authors state that one of the reasons for choosing a sample size of 1000 is “…to ensure that results from this study will be applicable to rural areas of Maharashtra state.”. This will need to be explained clearly. Specifically, the concern is with respect to (a) how would any sample size defined within a set of villages in one district of the state “…be applicable” to the entire state? Perhaps the authors seek to achieve analytical generalisability of their findings through mixed-method/qualitative inquiry and demonstrate the relative similarity of few/many/all other districts to this district with respect to the area of inquiry, but this cannot be based on a particular sample size in my assessment. It is also noted that another logic to arrive at the size has been the resource availability. On the contrary, could an effort at achieving a sampling strategy of smaller numbers of household visits be used to further minimize sample numbers if needed? I understand that the work may have already begun, in which case, authors need to clarify this section appropriately.

- Authors mention a stratified sampling approach, but the survey is being conducted by invitation to a “station” at each village. How will the 125 per each age-stratum and 500 from each gender be achieved if there is a patterning in age of children who turn up at the station (for instance, older boys being less “shy” of such a station, or for instance if some stations for reasons unknown are not acceptable/accessible for particular age/gender respondents). Given that the researchers do not identify specific strategies to ensure the sample across strata, this stratified sampling appears more to be a desire at ensuring distribution of sample across all age-groups rather than an actual sampling strategy? Clarify.

**RC program evaluation**
In terms of improving the coherence between these 2 objectives, and also given that both are being implemented in the same district, it is useful to understand if the 40 villages where RC will be evaluated are a sub-set of the 70 where the quantitative survey will be conducted?

The RC group in each village: Are these volunteers or paid staff of the project? Clarify.

Given that the objective is to evaluate an intervention which has multiple components, an overall evaluation approach to the intervention is missing. Partly, this could be dealt with by providing more details of how the qualitative data will be analyzed from the FGDs. Also to some extent, the evaluation will only engage with relative insiders (the village level RC group) and will not include perspectives of those who "received" the intervention, a limitation. Authors could consider including a clear schematic/narrative on how the intervention is expected to work outlining the various intervention inputs, assumptions being made and how it is linked to expected outputs of the intervention (akin to a theory of change). In the lack of such a theory, the qualitative data gathered may be difficult to coherently analyze. That said, if there is a plan for doing this in another way, authors could include that.

Data analysis

There is limited information on how quantitative and qualitative data will be analyzed. This will have implications on the data collection methods and sampling details proposed. Also, see above about evaluation component and (lack of) details of the analysis proposed.

Is the rationale for, and objectives of, the study clearly described?
Partly

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Public health, realist evaluation, health policy & systems research methods

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.
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