RESEARCH PROTOCOL

Bandebereho randomized controlled trial: a six-year follow-up

Assessing the longer-term impacts of a gender-transformative couples intervention on men's engagement in maternal, newborn, and child health, caregiving, and healthier couple relations

FEBRUARY 2021

PROMUNDO
Healthy Masculinity. Gender Equality.

RWAMREC
men working with women to promote gender equality

Abbreviations

ANC	Antenatal Care
ECD	Early Childhood Development
IMAGES	International Men and Gender Equality Survey
IPV	Intimate Partner Violence
IRR	Incidence Rate Ratio
OR	Odds Ratio
RCT	Randomized Controlled Trial
RMNH	Reproductive, Maternal and Newborn Health
RWAMREC	Rwanda Men's Resource Center
SRH	Sexual and Reproductive Health
SRHR	Sexual and Reproductive Health and Rights
VAC	Violence against children
VAW	Violence against women

Note to the Reader

This protocol was submitted to the National Institute of Statistics Rwanda (NISR) for research permissions prior to commencing the study. Some elements may differ from the final study implementation: the timeline was delayed due to the ongoing COVID-19 pandemic and restrictions in place at the time. The plan to collect anthropometric data from children included in the protocol was ultimately not feasible due to time and budgetary constraints. We have redacted the specific study locations to protect the confidentiality of participants.

This six-year follow-up was registered on Clinicaltrials.gov (NCT04861870) after approval of the protocol from the Rwanda National Ethics Committee (42/RNEC/2021), NISR (0093/2021/10/NISR), and the National Council for Science and Technology (NCST/482/223/2021) but prior to commencing the study.

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1. Introduction and background

There is growing evidence of the promise and potential of gender-transformative programs – which actively engage participants in reflecting on and challenging inequitable gender norms and power dynamics – with fathers to promote the health and well-being of their partners, children, and men themselves. The Bandebereho intervention works with men and couples to promote men's engagement in maternal and newborn health, equitable caregiving, healthier couple relations and the prevention of violence against women and children. The intervention, inspired by Promundo's Program P, was adapted to the Rwandan context by the Rwanda Men's Resource Center and Promundo, and approved by the Ministry of Health.

From 2013-2015, RWAMREC piloted Bandebereho with more than 3,500 parents in four districts (Karongi, Musanze, Nyaruguru, Rwamagana). Rwanda represented a strategic place to rigorously evaluate a gender-transformative male engagement approach. The country has made significant strides in reproductive and maternal health and the promotion of gender equality, and its policies acknowledge that progress on sexual, reproductive, and maternal health and violence prevention require interventions with men and couples to promote equitable gender relations, women's decision-making power, and reduced IPV.[i,ii]

1.1. Description of the intervention being evaluated

The Bandebereho couples' intervention being assessed was concluded in 2015. The intervention engaged men and their partners in participatory, small group sessions of critical reflection and dialogue. The intervention used a structured curriculum which was approved by the Rwanda Ministry of Health/Rwanda Biomedical Center. Men participating in the Bandebereho intervention were invited to 15 sessions (maximum 45 hours) and their partners to 8 (maximum 24 hours). Sessions addressed: gender and power; fatherhood; couple communication and decision-making; intimate partner violence; caregiving; child development; and male engagement in reproductive and maternal health.

The intervention creates a structured space for men and women to:

- question and critically reflect on gender norms and how these shape their lives;
- rehearse equitable and non-violent attitudes and behaviors in a comfortable space with supportive peers; and
- internalize these new gender attitudes and behaviors and apply them in their own lives and relationships.

Results from the evaluation showed that becoming aware of inequalities, reflecting on the costs of rigid norms, and learning and practicing new skills (e.g., couple communication and joint decision-making) in a safe, non-judgmental peer environment, lead to changes across a range of health and relationship behaviors.

Community volunteers (local fathers) met with the same group of 12 men/couples on a weekly basis. The volunteers received a two-week training, material support, and refresher trainings from RWAMREC. Local nurses and police officers co-facilitated the sessions on pregnancy, family planning, and local laws, respectively. Sessions were conducted in local schools and administrative offices. RWAMREC staff monitored implementation of the group sessions and mentored the facilitators. Three intervention cycles, each with 570–576 couples, were implemented between March 2014 and July 2015. The Bandebereho RCT assessed the third cycle. The control group received no group intervention, though it did have access to community activities and campaigns related to the broader MenCare+ project through which the Bandebereho couples' groups were implemented. The intervention has been documented in greater detail in Doyle et al (2018).

1.2 Previous evaluation findings

A randomized controlled trial (RCT) of the Bandebereho intervention was previously conducted with 1,199 couples (575 treatment; 624 control) and demonstrated significant impacts on a range of gender and health-related outcomes. As reported in PLOS One[iii], at 21-months after the baseline (16 months post-intervention), compared to a control group, participating families reported: less past-year physical (OR 0.37, p<0.001) and sexual intimate partner violence (IPV) (OR 0.34, p<0.001), and less physical punishment of children (women: OR 0.56, p = 0.001; men: OR 0.66, p = 0.005). Women in the intervention reported greater antenatal care (ANC) attendance (IRR 1.09, p<0.001) and male accompaniment to ANC (IRR 1.50, p<0.001), as well as modern contraceptive use (OR 1.53, p = 0.004), compared to women in the control group. Additionally, women in the intervention group reported higher levels of men's participation in childcare and household tasks (women: beta 0.39, p<0.001; men: beta 0.33, p<0.001) and less dominance of men in a series of household decisions. Forthcoming analyses also indicate that compared to the control group, the intervention group reported: lower rates of maternal depression, lower rates of men's alcohol consumption, and greater time spent by parents in stimulating interaction with their children.

The results of the Bandebereho RCT have contributed to critical evidence gaps on the impact of male engagement approaches. While several trials from the Global South had previously shown positive impacts on outcomes related to intimate partner violence (IPV),[iv,v,vi,vii,viii] family planning,[ix,x] and maternal health,[xi,xii,xiii] rigorous evidence of effectiveness of male engagement approaches has remained limited.[xiv,xv,xvi] In addition, few studies have evaluated interventions addressing multiple outcomes and even fewer have examined impact on household gender and power dynamics[xvii,xviii] in the way that the Bandebereho RCT has done. While the Bandebereho RCT collected data over a longer timeframe than many studies (at 16 months post-intervention), it does not provide an understanding of the longer-term impacts of the intervention.

1.3 Proposed research

We seek to conduct a six-year follow-up of the Bandebereho RCT to understand the longer-term impact of the intervention on participating couples. In addition, we wish to expand our study to incorporated direct observation of child development outcomes, to better assess the intervention's impact on children of participating couples. We know that young children's growth and development is particularly impacted by their relationships – or lack thereof – with caring, engaged, and responsive parents and caregivers. Children's highest potential is supported when they are raised in a home that is free from violence – against children and against their mothers – by caregivers who foster a sense of being loved, protected, and cared for, and who respect each other and share equitably the childrearing.

The results from the Bandebereho RCT – which indicated parents' reduced use of harsh or physical discipline against their children – suggest enormous promise for the intervention to have measurable impacts on the development and well-being of children through the transformation of the couple relationship and home environment. Violence can lead to severe consequences for children. In addition to the risk of immediate injury, studies have shown that exposure to extreme trauma and "toxic stress" during early developmental stages – including both experiencing violence and witnessing it – can severely damage the organization of the brain by disrupting proper development. Indeed, violence affects children's mental health, their learning and performance in school, and creates difficulties in developing empathy, controlling aggression, and interacting with others, and damages parent–child relationships.[xix,xx]

We have a unique opportunity to assess child outcomes as well as the sustainability of changes in the couple dynamics six years after the intervention began: few interventions in either the early child development field or the violence against women field have been able to track results over such a time frame. As attention to both early child development (ECD) and violence prevention increases, a longer-term study can provide much needed evidence. The six-year follow-up will add a unique and valuable contribution to the existing evidence on gender-transformative male engagement interventions, by: a) providing data on the longer-term impact of the intervention (including whether previous outcomes have been sustained), and b) providing data on if the intervention shows measurable impacts on children's cognitive and social and emotional development outcomes. In addition, Promundo and RWAMREC are currently working with the Rwanda Biomedical Center to scale-up the Bandebereho intervention via the health sector in Musanze district, by training more than 400 community health workers to implement the program as part of their routine health promotion work. The findings will strengthen and inform the ongoing scaling of the intervention.

2. Study objectives

This study is a six-year follow-up of the Bandebereho RCT. This round of data collection will be (up to) the fourth contact with study participants. Three previous rounds of data collection were

conducted as part of the Bandebereho RCT: a baseline in 2015, a 9-month follow up in 2015, and a 21-month follow up in 2016. In 2020, a phone survey focused on COVID-19 was conducted with a subsample of 500 men and 498 women enrolled in the study.

The aim of this study is to assess the longer-term, six-year impact of the gender-transformative Bandebereho intervention on participating couples and their children, when compared to the control group. The specific objectives of the study are:

a) To understand the longer-term impacts of the Bandebereho intervention on men's and women's behaviors and experiences, including caregiving, couple dynamics, parenting, reproductive health, and intimate partner violence.
b) To understand the impact of the Bandebereho intervention on young children's cognitive and social-emotional development.

A table of key indicators is included in Table 4.1: Primary Outcomes and Indicators, in Section 4.1.

3. Study Methodology

3.1. Study description

This study is designed as a six-year follow-up of the Bandebereho randomized controlled trial (RCT) to evaluate the longer-term impacts of the Bandebereho gender-transformative, couples' group intervention on participating men, their partners, and a sub-sample of children. The study design and sampling of adult participants are thus based on the original study design and sample, approved by NISR (9 February 2015, 0082/2015/NISR), the Rwanda National Health Research Committee (25 August 2014, NHRC/2014/PROT/0193), and the Rwanda National Ethics Committee (24 October 2014, 346/RNEC/2014).

3.2. Study design

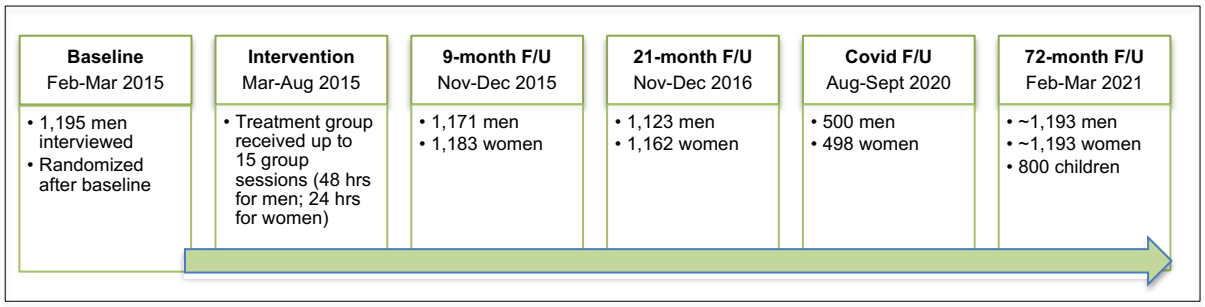
The study is designed as a six-year follow up of a randomized control trial with two arms: intervention and control. Couples were recruited into the intervention via the male partner in early 2015 and were later randomized to either the intervention or a control group. Due to the nature and structure of the intervention, randomization was done at the individual level. Randomization for the Bandebereho study took place in 2015, following the baseline survey (using the individual as the unit of randomization). The randomization was done by Laterite, an independent data collection firm, using a random number generator in Stata. Of the 1,199 men enrolled in the study, 575 men and their partners were randomized to the intervention (Bandebereho) group and 624 men and their partners were randomized to a control group, which received no intervention. Bandebereho community

facilitators notified men of their assignment. All recruited men remained eligible for randomization to the intervention regardless of participation in baseline data collection.

The flow diagram of the Bandebereho RCT is included as Appendix 2.

Data were previously collected at three time points: baseline (February/March 2015); 9-month follow-up (November/December 2015); and 21-month follow-up (November/December 2016). Data were also collected from a subsample of respondents by phone, in August 2020, to better understand the impact of the Covid-19 virus on their lives. The proposed six-year follow-up will collect data in April and May 2021, approximately 72 months post-baseline. The study will seek to conduct in-person surveys with all couples enrolled in the original study (who are alive and traceable) and to conduct child assessments with a sub-sample of 800 children from 800 families.

Figure 1. Bandebereho RCT timeline



3.3. Study site

The study site includes communities in 16 sectors within the 4 districts (Karongi, Musanze, Nyaruguru, and Rwamagana) where: a) the Bandebereho project was implemented from 2013-15, in collaboration with the Ministry of Health and local authorities; and b) where the previous rounds of data collection of the Bandebereho RCT took place. The sectors (4 per district) include:

- Karongi district (Western Province): [redacted]
- Musanze district (Northern Province): [redacted]
- Nyaruguru district (Southern Province): [redacted]
- Rwamagana district (Eastern Province): [redacted]

Data will also be collected from RCT participants who have relocated outside of these locations but are willing to travel to a data collection site to be surveyed.

3.4 Sampling

3.4.1. Sampling frame

The sampling frame for this study includes all participants from among the 1,199 couples (576 treatment; 624 control) who enrolled in the original RCT study in 2015, who are living, traceable, and remain eligible for the study. We will also conduct child assessments with a randomly selected sub-sample of 800 of their children born around or shortly after the intervention, aged between 4 and 7 years (400 treatment; 400 control).

3.4.2. Inclusion and exclusion criteria

This six-year follow-up seeks to survey all men who have participated in a previous round of data collection for the Bandebereho RCT and their current female partners. The original inclusion and exclusion criteria are described in Appendix 1. The inclusion and exclusion criteria for this round of data collection are outlined in Table 3.4.2. Note that all men who were recruited into the original study were older than 18 years; men may have new partners in this round of data collection, therefore their female partners must be at least 18 years old to be eligible. While women's inclusion is dependent on a current relationship with a man eligible for inclusion in the study, it does not depend on whether the male partner is surveyed at the six-year follow-up. The current study also seeks to measure child development outcomes on a subsample of children from enrolled couples, whose inclusion criteria are also described in Table 3.4.2.

Table 3.4.2: Inclusion and exclusion criteria for 6-year Bandebereho RCT follow-up

Study population	Inclusion criteria	Exclusion criteria
Men	a) Enrolled in the original Bandebereho RCT b) Participated in at least one (of three rounds) of previous RCT data collection conducted between 2015-16 c) Currently partnered (married or cohabiting) with a female partner d) Currently resides in the four districts included in the original study (Karongi, Musanze, Nyaruguru, Rwamagana), or is able to travel to one of these data collection sites	a) Resides outside of the sites selected for this study and specified follow-up locations, and is unable to travel to one of the data collection sites b) Unable to provide informed consent

Women	a) Currently partnered (married or cohabiting) with a man eligible for inclusion in the current study b) Currently resides in the four districts included in the original study (Karongi, Musanze, Nyaruguru, Rwamagana), or is able to travel to one of these data collection sites c) At least 18 years of age or older	a) If partner enrolled in the RCT is deceased b) Resides outside of the sites selected for this study and specified follow-up locations, and is unable to travel to one of the data collection sites c) Unable to provide informed consent
Children	a) Aged between 4 and 7 years; b) Biological child (of the male partner) living in the household of a man enrolled in the Bandebereho RCT; c) Whose parent has consented to the child's participation in the study d) Child provides assent to participate	a) If the child lives outside of the household (e.g. with other relatives, at an institution) b) If another child in the same family has been selected for assessment

3.4.3. Sample size calculation

We conducted a power analysis (in June 2014) to assess ability to detect intervention effects on selected outcomes. At the time, we found that the indicators would provide sufficient power, between 65% and 99%, depending on the indicator – please see Doyle et. al (2018) for additional detail. While we do expect greater attrition than in previous rounds, we had very high response rates and low attrition in the study thus far. At most recent data collection with the full sample, 21-months post-baseline, 94% of the men and 97% of the women were surveyed.

It is difficult to estimate effect sizes on children's outcomes in the context of a couples intervention rather than a targeted early childhood development intervention, and with limited data available. To determine the appropriate sample size for the child assessments, we consulted several experts through the Saving Brains Grand Challenges platform, who based on their expertise with the assessment tools and randomized trials of early childhood development programs, recommended a minimum sample size of 300-400 children per arm.

3.4.4 Sample selection

The primary sampling unit, and unit of analysis, is the individual respondent within the household. All men enrolled in the original Bandebereho RCT who are known to still be alive at the 21-month

follow-up (n=1,193) will be assessed for eligibility in the current study and included in the sample, as well as their current female partners.

For the six-year follow-up, we will be randomly selecting 800 households with children ages 4-7 for observational assessments of a selected child. The children will be selected randomly from a list of families with eligible children, stratified by intervention and control group status, as well as by district. Only one child per family would be eligible for assessment. If the family has more than one child ages 4-7, the child closest to age 6 would be selected. If more than one child fits that criterion (e.g. one child age 5 and another child age 7), the youngest child is selected. If the family has twins ages 4-7, one child is randomly selected.

Sampling will be done by Laterite, an external data collection firm.

4. Research instruments, outcome measurement and analysis plans

4.1 Research instruments and indicators

The outcomes assessed via men's and women's responses will be collected through a survey questionnaire, administered in-person by a team of sex-matched enumerators trained in survey administration and research ethics. Child outcomes will be assessed through standard structured observation and assessment tools previously used in Rwanda, by trained and experienced enumerators from Laterite. Children will be accompanied by a trusted adult (typically a parent), and for safety considerations and the comfort of both the child and the parent, will never be alone with the enumerator.

The research instruments will collect data on outcome measures related to five domains:

- **Reproductive, maternal, and newborn health (RMNH) and men's engagement**: women's attendance of antenatal care (ANC) visits; men's accompaniment and/or participation in ANC; and modern contraceptive use.
- **Gender attitudes and household dynamics**: attitudes about gender norms; men's participation in caregiving and domestic tasks; household division of labor and time spent on household tasks; men's dominance of household decision-making; couple communication; relationship dynamics and quarreling.
- **Intimate partner violence, risk behaviors, and men's and women's health and well-being**: intimate partner violence; attitudes about violence against women; men's alcohol use; stress, support, and mental health.

- **Parenting and parental self-efficacy**: couple division of childcare; time spent on childcare tasks; positive parenting behaviors such as stimulation, responsiveness, and positive discipline; use of violence and/or harsh discipline against children; attitudes about violence against children; feelings of parental self-efficacy.
- **Child development**: measures of social and emotional skills including prosocial behavior, conduct problems and peer relationships; executive functioning; emergent numeracy; and height and weight.

Data on children's outcomes will be collected from parent reports as well as through direct child observation and collection of anthropometric data. Child observations will be conducted with a sample of 800 children ages 4-7 (who would have been born in the period during or directly after the intervention). Table 4.1 presents the primary outcomes of interest and how they will be measured.

Table 4.1. Primary outcomes and Indicators

Primary Outcomes	Outcome	Respondents	Instrument, Indicators
Reproductive and maternal health behaviors	Women's antenatal care (ANC) attendance	Women	Women will be asked how many ANC visits they attended during their current pregnancy (if applicable) and during their most recent pregnancy.
	Men's accompaniment to ANC	Women; Men	Women will be asked how many times their partner accompanied them to ANC visits; men will be asked how many times they accompanied their partner.
	Modern contraceptive use	Women; Men	Women and men will be asked about their or their partner's current use of any modern contraceptive method (e.g., implant, injection, male or female condom, pill, IUD, vasectomy, hysterectomy).
Experiences of intimate partner violence	Women's past year experience of intimate partner violence	Women Women	Women will be asked items adapted from the WHO multi-country study[xxi], regarding how many times in the past 12 months their partner had: 1) slapped them or threw something at them that could hurt them; 2) pushed or shoved them; 3) hit them with a fist or with something else that could hurt them; 4) kicked, dragged, beat, choked or burned them; 5) threatened to use or actually used a knife or stick against them. Response options will include 0=never, 1=once, 2=a few times, and 3=frequently.

			Women will be asked how many times in the past 12 months: 1) their partner had forced them to have sex when they did not want to; and 2) they had consented to sex out of fear of what their partner might do if they refused. Response options will include 0=never, 1=once, 2=a few times, and 3=frequently.
Parenting behaviors	Physical punishment of children	Women; Men	Men and women will be asked items adapted from the Multiple Indicator Cluster Survey (MICS) child discipline module,[xxii] including whether or not they: 1) shook the child; 2) spanked, slapped or hit the child on the bottom with a bare hand; 3) hit the child on the bottom or elsewhere on the body with something like a belt, stick or other hard object; 4) hit or slapped the child on the face, head, or ears; 5) hit or slapped the child on the hand, arm, or legs; 6) beat the child up, meaning hit the child over and over as hard as one could; and 7) made the child kneel on the ground for a period of time. Response options will include 0=no, 1=yes.
	Parental stimulation, responsiveness and warmth	Women; Men	Parental warmth, responsiveness, and positive discipline behaviors will be assessed through the MICS early childhood module, and potentially the HOME or IDELA observation or parent questionnaire. These include questions on parental behaviors such as teaching the child something, playing with the child, praising the child, etc.
Child development	Social and emotional development Cognitive development and executive functioning	Women, men reporting on index child Child assessment	Parents will complete the Strengths and Difficulties questionnaire, which includes 25 items on children's internalizing problems, externalizing problems, and prosocial behaviors. Pending piloting, cognitive development, executive functioning, and social and emotional skills will be assessed by trained interviewers administering the International

			Development and Early Learning Assessment (IDELA), which has previously been used in Rwanda.
Gendered division of childcare and household tasks	Division of childcare and household tasks	Women; Men	Men and women will be asked how they divided a series of childcare and household tasks with their partner. Response options will be woman always does the task, task is shared equally or done together, man always does the task, someone else does it, or not applicable.
	Time spent on childcare, household tasks, and paid work	Women; Men	Respondents will be asked on how many days in the previous week they did each of a series of childcare, household tasks, and activities related to paid work, and how much time (in hours or fractions of hours) on average they spent on the task on each of those days.
Men's dominance in household decision-making	Men having the final say on key household decisions	Women; Men	Men and women will be asked who has the final say in making a series of family-related decisions. Response options will be self; partner; both have the same say; someone else; don't know.

Note that the six-year follow up findings may be confounded by subsequent participation of couples from the control group in the Bandebereho scale-up in Musanze district in 2020, and a similar program implemented under Rwamrec in Karongi district. Participants from these districts will be asked about their participation in these programs, and the results will be included in the analysis as appropriate.

We request permission to make minor changes to the tools based on pre-testing prior to data collection. Changes may include deletion of some items or rewording of items for clarity and relevance. No new domains and no entirely new instruments will be used without prior approval.

4.2. Proposed analysis

Proposed analyses include generating descriptive statistics on all variables, as well as examining differences between the intervention and control group participants on primary outcomes using t-test, chi2-tests, and generalized estimating equations with robust standard errors to account for clustering by facilitator.

5. Field work plans

5.1 Tracing RCT participants

For this six-year follow-up, we will begin by tracing the men enrolled in the original RCT study to confirm or update their contact information. RWAMREC, the local NGO who implemented the original Bandebereho intervention, will assist in tracing all male participants. RWAMREC staff knowledgeable of the intervention and the study sites will attempt to contact each individual by telephone using the phone number provided at the most recent Bandebereho RCT data collection in which he participated. RWAMREC staff will introduce the six-year follow-up study to men enrolled in the study, update contact information as needed (i.e. phone number, owner of the phone) and confirm the name and contact details for their current female partners (as applicable). When it is not possible to reach the respondent on the phone, RWAMREC staff will engage previous Bandebereho facilitators and local authorities to help in locating enrolled participants and providing updated contact information, before contacting them.

RWAMREC will provide the updated contact information to Laterite, an independent research firm, to contact participants to confirm eligibility and schedule interviews and child assessments.

5.2 Confirming eligibility and willingness to participate

Using the updated contact information, Laterite will use a team of enumerators to contact all male RCT participants to:

a. Confirm the respondent's identity;
b. Inform respondent of the current study aims and objectives and basic study details;
c. Confirm the respondent's eligibility for the follow-up study;
d. If eligible, invite respondent to participate in the six-year follow-up data collection;
e. If respondent is willing to participate, collect updated household demographic information (including name, gender, age and contact details of household members).

f. If there are children aged 4-7 in the household, screen for physical disabilities such as difficulties with speech, hearing, and sight or cognitive disabilities that would preclude the child's participation.
g. Inform the respondent that Laterite will be in touch to confirm the date, time and location of interview.

For any male RCT participants who are missing contact information or cannot be reached over the phone after several attempts, Laterite enumerators will visit their home on record. If the participant is found, enumerators will follow the process outlined above (a-f) to confirm in person eligibility and willingness to participate.

5.3 Scheduling appointments

For couples with separate contact information for each partner, enumerators will contact all male RCT participants who agreed to the follow up to inform them of the date, time, and location of the men's interview. Enumerators will then contact the female partners separately to inform them of the date, time, and location of the women's interview. If the family is selected for a child interview, both partners will also be informed of the date, time, and location for the child assessment and will be asked to bring a copy of their child's vaccination card to the interview to confirm the child's date of birth.

For couples with only one phone number, the enumerator will call and ask to speak to each partner individually to provide the interview information. If one partner is not available, the enumerator will ask the partner with whom they speak to relay the information to their partner.

On the day of the survey, informed consent will be obtained from each respondent according to the procedures described in section 6.2.

5.4 Enumerator training

In consultation with the investigators, Laterite will develop a training program for the field team – with adult interviewer and child assessment teams trained separately. The training will comprise six days of classroom instruction and two days of piloting.

Before the start of training, Laterite's data team will prepare a training agenda and field manual. The field manual will serve as a reference document used by the field team during training and fieldwork. The field manual will cover: (i) an introduction to the project, explaining the objectives and the methodology; (ii) an overview of team structure and responsibilities; (iii) a detailed description of professional code of conduct and ethical requirements; (iv) an explanation of the terms of the

contract; (v) data collection protocols; (vi) an overview of the research instruments, explaining the structure and flow of the questionnaire; (vii) details on procedures to follow during an emergency and relevant contact information; and (viii) adverse event and risk of harm reporting procedures.

Our training curriculum, which will be delivered mostly in Kinyarwanda, is tested and organized around the following modules:

- Introduction. The introduction will include a focus on: (i) the training objectives and agenda; (ii) a detailed explanation about the project; and (iii) an explanation about the study research objectives.
- Research methodology and sampling strategy. To perform well, it is important that the enumerator team understands the research methodology and the sampling strategy. This part of the training will be explained in a structured way: (i) how the study is set-up and the logic of the design; (ii) the sampling strategy and how participants are selected; and (iii) a discussion about the replacement strategy and the importance thereof.
- Field team structure and responsibilities. Everyone on the team needs to have a clear understanding of their roles and responsibilities. This module will focus on: (i) the mission and objective of the field team; (ii) the team structure, composition and responsibilities; (iii) the structure of the field plan; and (iv) reporting systems and requirements.
- Professional and research ethics. Ethics are paramount in all research projects. In this section our training will cover: (i) the general professional ethics that the field team should abide by; (ii) the rights of study participants; (iii) research ethics and etiquette; and (iv) what to do when an adverse event arises.
- Logistics. This module will focus on procedures for: (i) the safekeeping of field materials such as tablets, chargers, anthropometrics, power banks, consent forms; and (ii) accounting processes in terms of the tracking and reporting of fieldwork expenses.
- Contracts. Enumerators need to understand the terms of their contracts and what they are signing up to. During this module, we explain: (i) the structure of the contract and contract duration; (ii) payment modalities; (iii) performance expectations and the importance of integrity; and (iv) why we ask that enumerators provide evidence of personal health insurance coverage.
- Survey instruments. This part of the training combines an overview of the research instruments and the flow of questions with a deep-dive into the logic of individual survey questions. During this module, we provide targeted training on the questionnaire, putting a special emphasis on ensuring that the team is fully briefed on the logic of the questionnaire and on potential risks and biases. We alternate theoretical explanations and exercises in which trainees practice the questionnaire with each other and can clarify their doubts concerning any survey questions. The field team practices through exercises involving: (i) the self-completion of the survey; (ii) mock interviews in pairs; and (iii) live practices. Q&A sessions are organized throughout this process to ensure that enumerators can ask questions and have a detailed understanding of the questions.
- Child assessments. For the data collectors tasked with leading child assessments, Laterite will provide intensive hands-on training. The training will include guidance on the proper set up

and use of equipment (if any), how to prepare and work with children, and how to take and record observations. Like the training on the survey instruments, we will alternate theoretical explanations and demonstrations with practice exercises so enumerators can get more experience. Q&A sessions and supervisor observation will provide opportunities for anthropometrists to request guidance and get feedback.

- Quizzes. Our training sessions will include quizzes to ensure that enumerators understand the training material and are not going to the field unprepared. This will help our trainers re-emphasize points that have not been understood or provide extra support to enumerators that are lagging behind. Performance on the quizzes will determine whether enumerators will be included in the team or not, whether they will enter the team as alternates, and whether they qualify to be field coordinators.
- Feedback. Feedback is also sought from the field team in terms of: (i) how easy survey questions are to understand and their relevance to the local context; (ii) the quality of the translation into Kinyarwanda; as well as (iii) faulty logic in the coding of the survey.

5.5 Pilot

Ahead of starting data collection, Laterite will organize a study pilot to test enumerators in survey-like conditions. Pilot participants will be selected from ongoing Bandebereho program participants in Musanze District (who are not enrolled in the RCT). The households will have similar demographics to those included in the main sample. The pilot will follow the same data collection protocols as the main study.

The objective of the pilot will be to confirm that:

- Interview teams correctly list, sample and interview households in the enumeration area;
- Interview team members understand their roles;
- Interview team members understand, and correctly follow interviewing, assessment and measurement protocols; and
- Interview team members successfully collect high-quality data without major errors or issues.

The pilot will be run under real conditions and over a period of 2 days. At the end of each day of piloting, the Field Manager will meet with the team to collect feedback and list any issues that occurred during the interviews and measurement taking.

5.6 Data collection

All interviews and child assessments will be conducted at central venues, such as sector or cell offices, churches, or schools when not in session. The Laterite field team will search for interview

locations where we can assure the privacy of all respondents. Interviews with men, interviews with women, and child assessments will be conducted on different days.

Interviews with adults will be conducted by sex-matched enumerators. Child assessments and collection of anthropometric data will be conducted in the presence of a parent by female enumerators. For the child assessment team, Laterite will prioritize recruiting enumerators with caregiving experience and experience in conducting child assessments.

We anticipate that interviews with adults will take 120 minutes and assessments with children will take 30 minutes (40 minutes if anthropometric data (i.e., height and weight) are collected). Attention will be paid to schedule child assessment appointments when children are not in school, either during weekends or breaks or outside of their school shift.

All interviews will be conducted face-to-face. All data will be collected electronically to ensure quality and data security since paper-based collection has high risks of loss of confidential information. Data collection will be done using android tablets and the surveys will be encrypted and stored on a safe encrypted server location.

Laterite will assign field supervisors to oversee the implementation of fieldwork protocols and adherence to research ethics. The role of the field supervisor is to observe that field procedures are being properly followed, provide individualized feedback to enumerators, attend to adverse events and risks of harm, and conduct backchecks as needed.

5.7. Participant incentives

Participants will receive a 3000 RWF for transportation (per interview or child assessment) to enable their participation in the survey or child assessment to compensate for the time and expense of travel to the data collection sites. The incentive for the child assessment will be provided to the adult guardian who brings the child to the assessment.

5.8. Ethical considerations

5.8.1. Confidentiality

Confidentiality is a priority. The research team will not share names or other identifying information of study participants without explicit permission for project purposes. Identifying information will be kept separate from participants' survey and assessment responses, and data files will be stripped of any identifying information prior to sharing with others over email or other electronic means.

5.8.2. Informed consent and assent

We will seek informed consent from all adult participants in the study. All members of the data collection team, including enumerators, will be trained on ethical protections for human subjects research, including research with children, and on obtaining informed consent.

During the explanation of the study and consent process, participants will be provided with general information about the study (as well as contact information for study personnel) and possible benefits and costs, as well as their right not to participate or to withdraw from the study at any point without any repercussions, as detailed in the consent forms included in Appendices 3-4. The enumerator will obtain written consent from the respondent; participants who are not literate may provide a thumbprint to indicate consent. We will obtain consent/assent electronically from all participants surveyed - this includes an electronic signature captured via SurveyCTO. If the participant is illiterate, a photo of the thumb-printed consent form will be captured in SurveyCTO. Informed consent will be obtained in a location with auditory privacy: interviewers will find either a separate room or an indoor or outdoor area where they can speak privately with the interviewee(s).

Upon completion of the interview, all participants will be a copy of the consent form (if they choose).

Seeking parental consent: Parental consent will be sought from the parent accompanying the child on the day of the assessment, according to the parental consent form in Appendix 4. The child's participation is voluntary, and the enumerators will explain to the child what's going to happen in the assessments (as described in the child assessment tool in Appendix 8) and measurements and encourage them to participate.

5.8.3. Risk of Harm (adverse event) protocol

All steps to ensure a 'do no harm' approach will be taken to minimize any adverse effects of respondents' participation in the study and procedures are in place to refer respondents to services if needed.

The study will be conducted in accordance with international ethical guidelines on researching violence against women, including not interviewing members of the same household about IPV.[xxiii] As in the 9- and 21-month follow-ups, we will ask women about their experiences of IPV, but will not ask men about violence perpetration, and men will not be informed of the inclusion of questions about violence in the women's questionnaire. To minimize risk of harm, we will obtain men's consent to contact their partners and interviews with men and women will be conducted on different days. All participants will be offered a list of locally available support services after the interviews.

Laterite will recruit an enumerator team familiar with collecting data on sensitive topics, who have received training from professional counselors on collecting sensitive data as part of previous studies (either the previous Bandebereho RCT or other studies on gender-based violence and family dynamics in Rwanda).

Laterite takes child safeguarding seriously and has a policy in place to protect children. This policy includes best practices in recruitment, obtaining consent, and reporting adverse events when conducting research with children. See Appendix 5 Laterite Child Protection Policy.

A 'risk of harm' is defined as any occurrence that is observed during research that suggests that participants may be at risk or may have encountered abuse whether emotional, sexual, physical, social and/or financial.

During the interviews, risks of harm may emanate from participants' disclosures about abusive relationships, suicidal tendencies, or threats to harm others. In these cases, the research team has a responsibility to take necessary actions to protect participants from harm through the provision of appropriate referral services.

If the budget allows and anthropometric data (height and weight) are collected from children, the research team will also identify any children deemed at risk, i.e. in acute situations. An acute situation will be defined as a situation in which the respondent self-identifies or identifies his/her child as being in immediate danger, a child who meets initial screening criteria for severe acute malnutrition (sex-specific weight-for-height z-scores of less than -3 among children under 5) or severe thinness (sex-specific BMI-for-age z-scores less than -3 among children ages 5-7) based on WHO Growth Reference Data.

Laterite and the data collection team will take the following steps if a participant self-reports a risk of harm to self or others or if a parent identifies a risk of harm to their child:

- The enumerator will attempt to gather as much information as possible from the participant regarding the situation.
- The enumerator will fill out a risk of harm form with a description of the risk of harm case as reported by the participant.
- **In the event of a life-threatening situation** (for instance if a participant reports current suicidal thoughts or domestic abuse that puts the participant or their child's life in immediate danger):
    - the enumerator will reach out to RWAMREC staff for immediate referral.
    - RWAMREC staff (with experience working in the district where the respondent is located) will immediately contact the closest local leader to enable an immediate follow-up with the respondent to prevent and/or mitigate the risk of harm. RWAMREC and the local leader(s) will assess the situation and the most appropriate intervention (e.g., engagement of police, counselors) and intervene as quickly as possible.

- In the event of a non-life-threatening situation:
    - the enumerator will ask the participant if they agree to a referral to relevant services (e.g., police, counselling, etc.) prior to contacting RWAMREC staff.
    - RWAMREC staff (with experience working in the district where the respondent is located) will follow-up with the respondent to connect him/her to the relevant service in a safety and privacy.

Laterite will review and report risks of harm to Promundo, RWAMREC and RNEC within 48 hours.

All adult study participants, regardless of whether they disclose a risk of harm, will be offered a list of referral services at the end of the interview.

5.9. Data Management

Data for both adult interviews and child assessments will be captured on SurveyCTO software on a tablet. Survey data will be encrypted, data will be collected on password protected individual devices, and data will be uploaded to the SurveyCTO server on a daily basis by the enumerators.

During training for the data collection team, Laterite will emphasize the importance of keeping information confidential and not disclosing information that is shared during interviews and/or child assessments.

Each interview or child assessment will be assigned the unique ID originally assigned in 2015, and participants' identifying information (name, contact information) linked to the ID will be kept separately from the rest of the data, in case the information is needed again for follow-up data collection rounds. The purpose of collecting identifying information is to confirm the identity of the respondent, link the data to previous rounds of data collection, and to allow for follow-up.

When analyzing data, only the participant ID will be available. Matching IDs to names will only be possible for the senior research team with access to the files. Data collectors will temporarily have access to this information as needed for data collection, but will not retain any of it.

Once identifying information has been removed from the data files, the data will be available for analysis and considered joint intellectual property between RWAMREC and Promundo. After the primary outcomes have been analyzed and published, the dataset will be available by request, with priority to Rwandan researchers.

Segments of the interviews or child assessments may be recorded and photos of children's vaccination cards will be taken for data quality monitoring purposes. The audio records and photos will be uploaded to the Laterite secure server along with completed interviews. Once they are

reviewed by the data quality team, all audio records and photos will be destroyed. No identifiable information or sensitive data will be covered in the audio recordings.

Participant or parental consent will be sought before recording any portion of an interview or taking a photo of a vaccination card.

6. Timetable

Activity	2020				2021									
	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct
Develop and translate study tools														
Finalize Protocol														
Submit protocol for RNEC review														
Revise protocol and resubmit if needed														
Submit protocol for NISR review and expected approval														
Submit protocol for NCST review and expected approval														
Pretest questionnaires and child assessment tools														
Begin tracing participants (once ethical approval in place)														
Recruit and train data collectors & supervisors														
Data collection														
Data cleaning and analysis														
Reporting and dissemination (ongoing beyond 2021)														

Appendices

The following documents are attached to this protocol as appendices:

- Appendix 1: Original Bandebereho RCT inclusion and exclusion criteria
- Appendix 2: Bandebereho RCT Flow Diagram
- Appendix 3: Adult Survey Consent Form in English / Kinyarwanda
- Appendix 4: Parental Consent Form for child assessment in English / Kinyarwanda
- Appendix 5: Laterite's Child Protection Policy
- Appendix 6: Men's Questionnaire in English / Kinyarwanda
- Appendix 7: Women's Questionnaire in English/Kinyarwanda
- Appendix 8: Child Assessment Tools in English / Kinyarwanda
- Appendix 9: CVs of relevant individuals

References

[i] Government of Rwanda. Fourth Health Sector Strategic Plan July 2018-June 2024. Ministry of Health. 2018.

[ii] Government of Rwanda. Maternal Newborn and Child Health Strategic Plan 2018-2024. Ministry of Health. 2018.

[iii] Doyle K, Levtov RG, Barker G, Bastian GG, Bingenheimer JB, Kazimbaya S, et al. (2018) Gender-transformative Bandebereho couples' intervention to promote male engagement in reproductive and maternal health and violence prevention in Rwanda: Findings from a randomized controlled trial. PLoS ONE 13(4): e0192756. https://doi.org/10.1371/journal.pone.0192756

[iv] Jewkes R, Nduna M, Levin J, Jama N, Dunkle K, Puren A, et al. Impact of Stepping Stones on incidence of HIV and HSV-2 and sexual behaviour in rural South Africa: cluster randomised controlled trial. BMJ. 2008; 337: a506. https://doi.org/10.1136/bmj.a506 PMID: 18687720

[v] Wagman JA, Gray RH, Campbell JC, Thoma M, Ndyanabo A, Ssekasanvu J, et al. Effectiveness of an integrated intimate partner violence and HIV prevention intervention in Rakai, Uganda: analysis of an intervention in an existing cluster randomised cohort. Lancet. 2015; 3: e23–33.

[vi]Hossain M, Zimmerman C, Kiss L, Abramsky T, Kone D, Bakavoko-Topolska M, et al. Working with men to prevent intimate partner violence in a conflict-affected setting: a pilot cluster randomized con- trolled trial in rural Coˆte d'Ivoire. BMC Public Health. 2014; 14: 339. https://doi.org/10.1186/1471-2458- 14-339 PMID: 24716478

[vii] Abramsky T, Devries K, Kiss L, Nakuti J, Kyegombe N, Starmann E, et al. Findings from the SASA! Study: a cluster randomized controlled trial to assess the impact of a community mobilization interven- tion to prevent violence against women and reduce HIV risk in Kampala, Uganda. BMC Med. 2014; 12:122. https://doi.org/10.1186/s12916-014-0122-5 PMID: 25248996

[viii] Raj A, Ghule M, Ritter J, Battala M, Gajanan V, Nair S, et al. Cluster Randomized Controlled Trial Evaluation of a Gender Equity and Family Planning Intervention for Married Men and Couples in Rural India. PLoS ONE. 2016; 11: e0153190. https://doi.org/10.1371/journal.pone.0153190 PMID: 27167981

[ix] Ibid.

[x] Shattuck D, Kerner B, Gilles K, Hartmann M, Ng'ombe T, Guest G. Encouraging Contraceptive Uptake by Motivating Men to Communicate About Family Planning: The Malawi Male Motivator Project. Am J Public Health. 2011; 101: 1089–95. https://doi.org/10.2105/AJPH.2010.300091 PMID: 21493931

[xi] Kunene B, Beksinka M, Zondi S, Mthembu N, Mullick S, Ottolenghi E, et al. Involving Men in Maternity Care South Africa. Washington, DC: Population Council, 2004.

[xii] Mullany BC, Becker S, Hindin MJ. The impact of including husbands in antenatal health education ser- vices on maternal health practices in urban Nepal: results from a randomized controlled trial. Health Educ Res. 2007: 22: 166–76. https://doi.org/10.1093/her/cyl060 PMID: 16855015

[xiii] Midhet F, Becker S. Impact of community-based interventions on maternal and neonatal health indica- tors: Results from a community randomized trial in rural Balochistan, Pakistan. Reprod Health. 2010; 7: 30. https://doi.org/10.1186/1742-4755-7-30 PMID: 21054870

[xiv] WHO. WHO recommendations on health promotion interventions for maternal and newborn health 2015. Geneva: World Health Organization; 2015.

[xv] Dworkin S, Treves-Kagan S, Lippman SA. Gender-Transformative Interventions to Reduce HIV Risks and Violence with Heterosexually-Active Men: A Review of the Global Evidence. AIDS Behav. 2013; 17: 2845–63. https://doi.org/10.1007/s10461-013-0565-2 PMID: 23934267

[xvi] Ellsberg M, Arango DJ, Morton M, Gennari F, Kiplesund S, Contreras M, et al. Prevention of violence against women and girls: what does the evidence say? Lancet. 2015; 385: 1555–66. https://doi.org/10. 1016/S0140-6736(14)61703-7 PMID: 25467575

[xvii] Hossain M, Zimmerman C, Kiss L, Abramsky T, Kone D, Bakavoko-Topolska M, et al. Working with men to prevent intimate partner violence in a conflict-affected setting: a pilot cluster randomized con- trolled trial in rural Coˆte d'Ivoire. BMC Public Health. 2014; 14: 339. https://doi.org/10.1186/1471-2458- 14-339 PMID: 24716478

[xviii] Kyegombe N, Abramsky T, Devries KM, Starmann E, Michau L, Nakuti J, et al. The impact of SASA!, a community mobilization intervention, on reported HIV-related risk behaviors and relationship dynamics in Kampala, Uganda. J Int AIDS Soc. 2014; 17:19232. https://doi.org/10.7448/IAS.17.1.19232 PMID: 25377588

[xix] Sachs-Ericsson, N., Plant, E. , A. , Blazer , D. , Arnow , B. (2005). Childhood sexual and physical abuse and the 1-year prevalence of medical problems in the national comorbidity survey. Health Psychology, 24, (1): 32-40.

[xx] Levtov R., van der Gaag N., Greene M., Kaufman M., and Barker G. (2015). State of the World's Fathers: A MenCare Advocacy Publication. Washington, DC: Promundo, Rutgers, Save the Children, Sonke Gender Justice, and the MenEngage Alliance.

[xxi] Garcıa-Moreno C, Jansen HAFM, Ellsberg M, Heise L, Watts C. WHO multi-country study on women's health and domestic violence against women: initial results on prevalence, health outcomes and women's responses. Geneva: World Health Organization; 2005.

[xxii] MICS surveys can be accessed at http://mics.unicef.org/surveys.

[xxiii] Watts C, Heise L, Ellsberg M, Garcia-Moreno C. Putting Women's Safety First: Ethical and Safety Recommendations for Research on Domestic Violence against Women. Geneva: World Health Organization; 2001.