



A social empowerment intervention to prevent intimate partner violence against women in a microfinance scheme in Tanzania: findings from the MAISHA cluster randomised controlled trial

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Summary

Background Globally, about 30% of women have experienced physical or sexual violence, or both, from an intimate partner during their lifetime. Associations between poverty and women's increased risk of intimate partner violence have been observed. We therefore aimed to assess the effect of a violence prevention intervention delivered to women participating in a group-based microfinance scheme in Tanzania.

Methods We did a cluster randomised controlled trial among women taking part in a microfinance loan scheme in Mwanza city, Tanzania. A microfinance loan group was only enrolled if at least 70% of members consented. We randomly assigned the microfinance groups in blocks of six to receive either the intervention (ie, the intervention arm) or be wait-listed for the intervention after the trial (ie, the control arm). Women in both arms of the trial met weekly for loan repayments. Only those in the intervention arm participated in the ten-session MAISHA intervention that aims to empower women and prevent intimate partner violence. Given the nature of the intervention, it was not possible to mask participants or the research team. The primary outcome was a composite of reported past-year physical or sexual intimate partner violence, or both. Secondary outcome measures were past-year physical, sexual, and emotional intimate partner violence; acceptability and tolerance of intimate partner violence; and attitudes and beliefs related to intimate partner violence. These outcomes were assessed 24 months after the intervention. An intention-to-treat analysis was done, adjusting for age, education, and baseline measure of the respective outcome. The study is registered with ClinicalTrials.gov, number NCT02592252.

Findings Between September, 2014, and June, 2015, 66 (65%) of 101 microfinance groups approached in the study area met the trial eligibility criteria and were enrolled, of which 33 (n=544 women) were allocated to the intervention arm and 33 (n=505 women) to the control arm. Overall, 485 (89%) of 544 women in the intervention arm and 434 (86%) of 505 in the control arm completed the outcomes assessment. Among the intervention arm, 112 (23%) of 485 women reported past-year physical or sexual intimate partner violence, or both, compared with 119 (27%) of 434 in the control arm (adjusted odds ratio [aOR] 0.69, 95% CI 0.47–1.01; p=0.056). Women in the intervention arm were less likely to report physical intimate partner violence (aOR 0.64, 95% CI 0.41–0.99; p=0.043) and were less likely to express attitudes accepting of intimate partner violence (0.45, 0.34–0.61; p<0.0001) or beliefs that intimate partner violence is a private matter (0.51, 0.32–0.81; p=0.005) or should be tolerated (0.68, 0.45–1.01; p=0.055). There was no evidence of an effect on reported sexual or emotional intimate partner violence. There were no reports that participation in the trial had led to new episodes of violence or worsening of ongoing violence and abuse.

Interpretation Reported physical or sexual intimate partner violence, or both, was reduced among women who participated in the intervention arm, although the effect was greater for physical intimate partner violence, suggesting that intimate partner violence is preventable in high-risk settings such as Tanzania.

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Introduction

Worldwide, almost one-third of ever-partnered women have experienced physical or sexual violence, or both, by an intimate partner.^{1,2} The negative effects of intimate partner violence on both women and their families' health are considerable.^{2,4} Furthermore, evidence is accumulating

for an association between intimate partner violence and incident HIV infection among women.^{5,6}

Ending all forms of violence and other forms of abuse against women and girls is crucial to accelerating sustainable development⁷ and curbing the HIV epidemic, which in many African countries is set against a backdrop

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Research in context

Evidence before this study

Meta-analyses of population data surveys suggest that, worldwide, 30% of women who have been in a relationship have experienced physical or sexual violence, or both, by an intimate partner. In east Africa, as elsewhere, population surveys not only suggest that prevalence of ever experiencing intimate partner violence are high among women but that ongoing levels of violence are also high.

As well as being a human rights abuse, intimate partner violence has a range of short-term and long-term effects on women's physical and mental health. As part of the 2015 *Lancet* Series on combating violence against women and girls, Ellsberg and colleagues synthesised existing reviews of evidence for violence prevention interventions, concluding that rigorous data for what works to prevent violence is skewed towards studies done in high-income countries with intervention research focused more on response than prevention.

The review also highlighted the growing body of rigorous evidence from sub-Saharan Africa showing that intimate partner violence is preventable. One of the first randomised controlled trials from sub-Saharan Africa was the Intervention with Microfinance for AIDS and Gender Equity (IMAGE), which was implemented in rural South Africa. The trial assessed the effect of a combined microfinance and ten-session participatory gender and HIV awareness intervention and showed that, 2 years after delivery of the intervention, women's reported experience of past-year physical or sexual intimate partner violence, or both, was reduced by 55%. This trial was influential in showing substantial effects on women's experience of intimate partner violence within a usual programmatic timeframe. However, it also raised questions. These questions included whether the effect achieved was due to the microfinance component or to the ten-session gender awareness component, or both, and whether similar effects could be achieved if the intervention was replicated in other settings.

Added value of this study

The MAISHA trial sought to respond to these issues by assessing whether an adapted ten-session social empowerment

intervention could be integrated into an existing microfinance programme in Mwanza city, Tanzania, and have an effect on women's past-year experience of physical or sexual intimate partner violence, or both. Rather than comparing an IMAGE-type intervention (ie, combined economic and social empowerment intervention) with no intervention, this trial assessed whether combining a social empowerment intervention with microfinance affected participants' experiences of past-year intimate partner violence compared with microfinance alone. About two-thirds of women in the intervention arm participated in at least seven of the ten sessions, suggesting the intervention was acceptable. The findings are positive despite a high baseline prevalence, in which reported physical or sexual intimate partner violence was lower among women who participated in the MAISHA intervention than those who received microfinance alone, although the observed effect was greater for physical intimate partner violence than for sexual intimate partner violence. There was evidence for a greater impact among women who participated in seven or more of the ten intervention sessions. These findings add to evidence that a social empowerment intervention combined with economic empowerment can directly reduce women's experience of intimate partner violence.

Implications of all the available evidence

This trial provides convincing evidence that a relatively short intervention integrated into an existing economic empowerment platform can reduce intimate partner violence, supporting the rationale of adding social empowerment interventions. An economic analysis will provide data for the cost and cost-effectiveness of the MAISHA intervention. Further analyses are planned, utilising complementary qualitative data, to explore women's experiences of the intervention and format, the process of change, and potential reasons for its effect on different forms of violence and abuse. Given the high prevalence of intimate partner violence observed in this and other studies, the MAISHA intervention has the potential to positively affect the lives of a large number of women in settings where intimate partner violence is common.

of gender inequalities and high prevalence of violence.⁶ Although evidence is now starting to emerge for effective prevention interventions,⁸ rigorous data for what works remain scarce.⁹ Furthermore, data are highly skewed towards studies done in high-income countries with intervention research focused more on response than prevention.⁸

Given the associations between poverty and women's increased risk of intimate partner violence, prevention research has focused on empowering women economically. In a recent review of economic interventions to prevent intimate partner violence or HIV risk behaviours,¹⁰ the authors found that positive outcomes were more likely when economic strengthening was combined

with gender transformative interventions. Among 11 studies that evaluated combining a gender transformative intervention with microfinance, seven were from sub-Saharan Africa, including the Intervention with Microfinance for AIDS and Gender Equity (IMAGE) study, which was developed in rural South Africa and combines group-based microfinance with a participatory gender and HIV training programme. In a cluster randomised controlled trial, IMAGE was shown to reduce women's past-year experience of physical or sexual intimate partner violence, or both, by 55%.¹¹ In secondary analyses to investigate the extent to which the observed effect on intimate partner violence was attributable to the different intervention components,

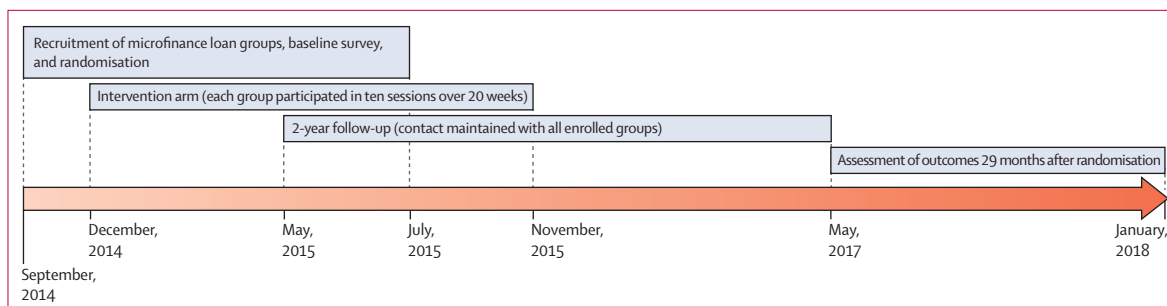


Figure 1: MAISHA trial timeline

The trial was done following WHO guidance on researching violence against women. During the trial, participants were provided with information about local support services for women experiencing relationship difficulties, including violence. Women who requested help were supported by the trial team to access local services.

only the combined intervention was associated with consistent reductions in different indicators of violence. When microfinance only was compared with no intervention, the direction of the intervention effects varied across the different violence indicators suggesting that the participatory gender training component of IMAGE is important in broadening the health and social effects of economic interventions.¹²

High prevalence of intimate partner violence has been reported in Tanzania, with nearly 30% of ever-partnered women reporting past-year physical or sexual violence, or both, from a partner.¹³ Recent demographic and health surveys indicate that high rates of intimate partner violence are ongoing in Tanzania.^{14,15} Inspired by the IMAGE study, we aimed to better understand the relative and combined effects of economic empowerment and social empowerment interventions in Tanzania on women's experiences of intimate partner violence. In this study, we assessed the effects of a social empowerment intervention on experiences of intimate partner violence among women taking part in a microfinance loan scheme,¹⁶ whereas in a separate ongoing study we are investigating these same effects among newly formed groups of women not engaged in a formal microfinance loan scheme.

Methods

Study design and participants

We did a cluster randomised controlled trial among women taking part in a microfinance loan scheme in Mwanza city, north-western Tanzania, in collaboration with BRAC, an established microfinance provider in Tanzania. Details of the study background, design and methods, and baseline characteristics of participants are described in detail elsewhere.^{16,17}

BRAC provides microfinance loans to women of low socioeconomic status with no access to formal financial services. Women are organised in groups and meet every week to repay part of their loan. Established microfinance groups were eligible for inclusion in the trial if there were fewer than 30 active members and there was a good meeting attendance (ie, repayment) record. Research staff met with potentially eligible groups to explain the

purpose of the trial and procedures. Group members were informed that half the groups enrolled would take part in a ten-session programme covering issues such as women's roles in the community and domestic violence. If the group expressed interest in taking part, each group member met with a research staff member to go through the participant information sheet, and have an opportunity to ask questions and seek clarifications (appendix pp 3–5). Women who agreed to participate and demonstrated comprehension of the trial procedures were invited to sign the consent form (appendix p 6). A microfinance loan group was only enrolled if at least 70% of members provided written informed consent. For each microfinance loan group enrolled, only members who consented to take part were interviewed.

It was anticipated that any harm to the women as a result of taking part in the trial would be minimal. WHO recommendations¹⁸ on researching violence against women were followed. Regular contact was maintained with participants throughout the trial, and a referral system was set up for women who reported experiencing violence to assist them with accessing appropriate services and support. Information about local support services was provided to all participants irrespective of whether they reported experiencing violence.

The trial was approved by the Tanzanian National Health Research Ethics Committee of the National Institute for Medical Research (reference NIMR/HQ/R.8a/Vol IX/1512), and the London School of Hygiene & Tropical Medicine research ethics committee (reference 11642). The MAISHA trial was implemented by the Mwanza Intervention Trials Unit, the Tanzania National Institute for Medical Research, and the London School of Hygiene & Tropical Medicine in close collaboration with local leaders and members of the communities where the trial was done.

Randomisation and masking

Microfinance loan groups were randomly allocated in blocks of six groups. Community randomisation ceremonies were done as a two-stage process that was both participatory and transparent involving the research team and representatives nominated by members from

See Online for appendix

For the protocol of the second ongoing MAISHA trial see <http://strive.lshtm.ac.uk/resources/cluster-randomised-controlled-trial-assess-impact-intimate-partner-violence-10-session>

For BRAC see <http://www.brac.net/>

1 Introduction and understanding gender
<ul style="list-style-type: none"> • What is meant by gender and sex? • How can gender norms affect women's health and wellbeing?
2 Act like a man, act like a woman
<ul style="list-style-type: none"> • What are common gender norms for men and women? • How can inequitable gender norms contribute to negative outcomes such as HIV and violence? • How can inequitable gender norms be changed?
3 Healthy and unhealthy relationships
<ul style="list-style-type: none"> • What are healthy and unhealthy behaviours that exist within relationships? • What are the characteristics of healthy relationships? • What are intolerable relationship behaviours?
4 Power in relationships
<ul style="list-style-type: none"> • What is it like to have power (ie, control) over someone and to be controlled by someone? • What is power and how can it be used to help or control someone? • What areas for your life would you like to have more power on and how can this be obtained?
5 Negotiating men's and women's roles inside and outside the home
<ul style="list-style-type: none"> • What are the roles, responsibilities, and workloads for men and women in the family? • How much time do women spend caring for themselves and for others? • What are the implications of women's heavy workload for their health and wellbeing? • Is the division of labour between men and women in the home fair, healthy, or "natural"?
6 Communicating assertively with your partner
<ul style="list-style-type: none"> • What is communication and what are the phases of communication? • What is the difference between passive, aggressive, and assertive communication? • How can "I" statements be used to communicate assertively?
7 What is violence?
<ul style="list-style-type: none"> • How do we define violence? • What are the different forms of violence against women? • What impact does violence against women have on couples, families, and communities? • What are the alternatives to violence?
8 Setting personal boundaries
<ul style="list-style-type: none"> • Why is it important to know what your personal boundaries are? • What is meant by sexual consent? • How can you use assertive communication to consent or not to consent to sexual activities?
9 Non-violent ways to resolve conflict
<ul style="list-style-type: none"> • How do childhood observations of conflict influence how you resolve conflict as an adult? • What are fair arguing rules? • How can you use assertive communication to make complaint?
10 Empowering change
<ul style="list-style-type: none"> • How can we challenge violence in our communities in ways that are productive and safe? • How can we provide support to victims of violence in our communities? • What are the benefits to challenging violence against women to the community and to women?
<div style="display: flex; align-items: center;">  <div style="margin-left: 10px;"> <p>The intervention ends with a candle ceremony <i>When someone's flame is low, we can lend our flame to that person</i></p> <p>During the ceremony, participants:</p> <ul style="list-style-type: none"> • Share key learning from the previous 20 weeks • Make personal commitments for the future </div> </div>

each of the groups to be randomly assigned. First, representatives from each of the six groups were randomly divided equally into two sets (ie, A and B). This process was done by each representative drawing a folded sheet of paper with A or B written on it from a box. Second, one representative was asked to call heads or tails for a coin-toss for her set of three groups to be allocated to immediate intervention. A trial team member then tossed a coin to randomly allocate each set of three groups to either immediate intervention (ie, the intervention arm) or to be wait-listed for the intervention after the trial (ie, the control arm). Given the nature of the intervention, it was not possible after assignment to mask participants or the research team involved in day-to-day operations and delivery of the intervention.

Procedures

Figure 1 outlines the trial timeline. Before randomisation, we did a face-to-face interview. The violence questions we included in our questionnaire were adapted from the WHO Violence Against Women instrument,¹³ which has also been widely used in demographic and health surveys and other prevention intervention trials of intimate partner violence.^{11,19,20} The questionnaire was translated into the local language (ie, Swahili) and independently translated back into English for validation. Interviews were done in private by female interviewers trained in interviewing techniques, gender issues, violence, and ethical issues related to research on intimate partner violence.²¹

The microfinance loan scheme was implemented by BRAC independently of the research team. Women in both arms of the trial met weekly for loan repayments, following BRAC procedures. On alternate weeks, either before or after the loan group meeting, groups allocated to the intervention arm participated in the ten-session MAISHA intervention following the *Wanawake Na Maisha* curriculum, which means women and life in Swahili (figure 2). This curriculum was developed by EngenderHealth (an international non-profit organisation focusing on gender equity and reproductive health) in collaboration with the research team, drawing on other published curricula, including Sisters for Life from the IMAGE study.¹¹ The MAISHA intervention was designed to be participatory and reflective, and aimed to empower women, prevent intimate partner violence, and promote healthy relationships by increasing knowledge and awareness (eg, of the consequences of normative attitudes to gender and intimate partner violence), developing relationship skills (eg, communication and

Figure 2: MAISHA intervention—ie, the *Wanawake Na Maisha* curriculum
 Sessions were designed to be interactive using a variety of approaches including small and large group discussions, small and large group exercises, role plays, and skills practice. Participants were encouraged to share their views and experiences, and to exchange ideas on the session topics.

Panel: Questions used to construct the primary and secondary outcomes**Physical intimate partner violence**

Reported that her current or any other partner has done at least one of the following to her in the past 12 months:

- Slapped or thrown something at her that could hurt her
- Pushed or shoved her, or pulled her hair
- Hit her with his fist or something else that could hurt her
- Kicked, dragged, or beat her up
- Choked or burnt her on purpose
- Threatened to use or actually used a gun, knife, or other weapon against her

Sexual intimate partner violence

Reported that at least one of the following has happened to her in the past 12 months:

- Current or any other partner forced her to have sexual intercourse by threatening her, holding her down, or hurting her in some way
- She had sexual intercourse when she did not want to because she was afraid that her partner would hurt her or someone she cared about if she refused
- She had sexual intercourse when she did not want to because she was afraid that her partner would leave her or take another girlfriend if she refused

Physical or sexual intimate partner violence

Reported that she had experienced physical or sexual intimate partner violence, or both, in the past 12 months (composite of the above two outcomes)

Emotional abuse*

Reported that her current or any other partner has done at least one of the following to her in the past 12 months:

- Insulted her or made her feel bad about herself

- Belittled or humiliated her in front of other people
- Done things to scare or humiliate her on purpose (eg, by the way he looked at her or by yelling and smashing things)
- Verbally threatened to hurt her or someone she cares about

Disclosure of intimate partner violence†

Reported that she has told someone within the past 12 months about her partner's behaviour (violence or abuse) towards her

Attitudes accepting of intimate partner violence

Reported that she strongly agrees or agrees that a man has good reason to hit his wife in at least one of the following scenarios:

- She does not complete her household work to his satisfaction
- She disobeys him
- She refuses to have sexual intercourse with him
- She protests because he has other girlfriends
- He suspects that she is unfaithful in marriage
- He finds out that she has been unfaithful in marriage

Believes a woman should tolerate violence in order to keep her family together

Reported that she strongly agrees or agrees with the statement:

- A woman should tolerate violence in order to keep her family together

Believes intimate partner violence is a private matter

Reported that she strongly agrees or agrees with the statement:

- Violence between husband and wife is a private matter and others should not intervene

*High intensity emotional abuse defined as having experienced at least one of the items many times in the past 12 months. †Among women who experienced physical or sexual intimate partner violence, or both, in the past 12 months.

conflict resolution), and improving group dynamics and stability (eg, increased peer support and social capital).

The ten-session MAISHA intervention was delivered over a 20-week period to the intervention arm groups at a venue convenient to participants. Generally, women met at the group chair woman's house or in a quiet area of a local café or guesthouse. Each session lasted 1.5–2 h, and was delivered by trained female facilitators following the *Wanawake Na Maisha* curriculum, which provides detailed guidance for each session. Facilitators were recruited and trained by the research team and EngenderHealth. Training was extensive allowing facilitators time to become very familiar with the curriculum materials and to practise and develop effective facilitation skills. Refresher training was provided by EngenderHealth during the trial. The trial coordinator and senior research team members monitored delivery of the intervention. To minimise contamination (ie, women in the control arm being exposed to the intervention), the curriculum facilitators only worked with intervention arm groups and maintained session attendance registers to ensure

the intervention was delivered to women only in the intervention arm, as well as to monitor attendance.

The research team maintained regular contact with both intervention and control groups during the 2-year follow-up to minimise losses. During this time, BRAC operations continued but with no further intervention from the research team. The effect of the intervention was assessed through interviews done 29 months after randomisation (24 months after groups completed intervention activities). Interviews were done face-to-face using the same structured questionnaire as at baseline, and following the same procedures. *Wanawake Na Maisha* curriculum facilitators were not involved in collection of baseline data or trial outcome assessments.

Outcomes

The panel presents details of questionnaire items used to construct the outcomes. The primary outcome was a composite of women's reported past-year experience of physical or sexual intimate partner violence, or both, among ever-partnered women at 29 months after

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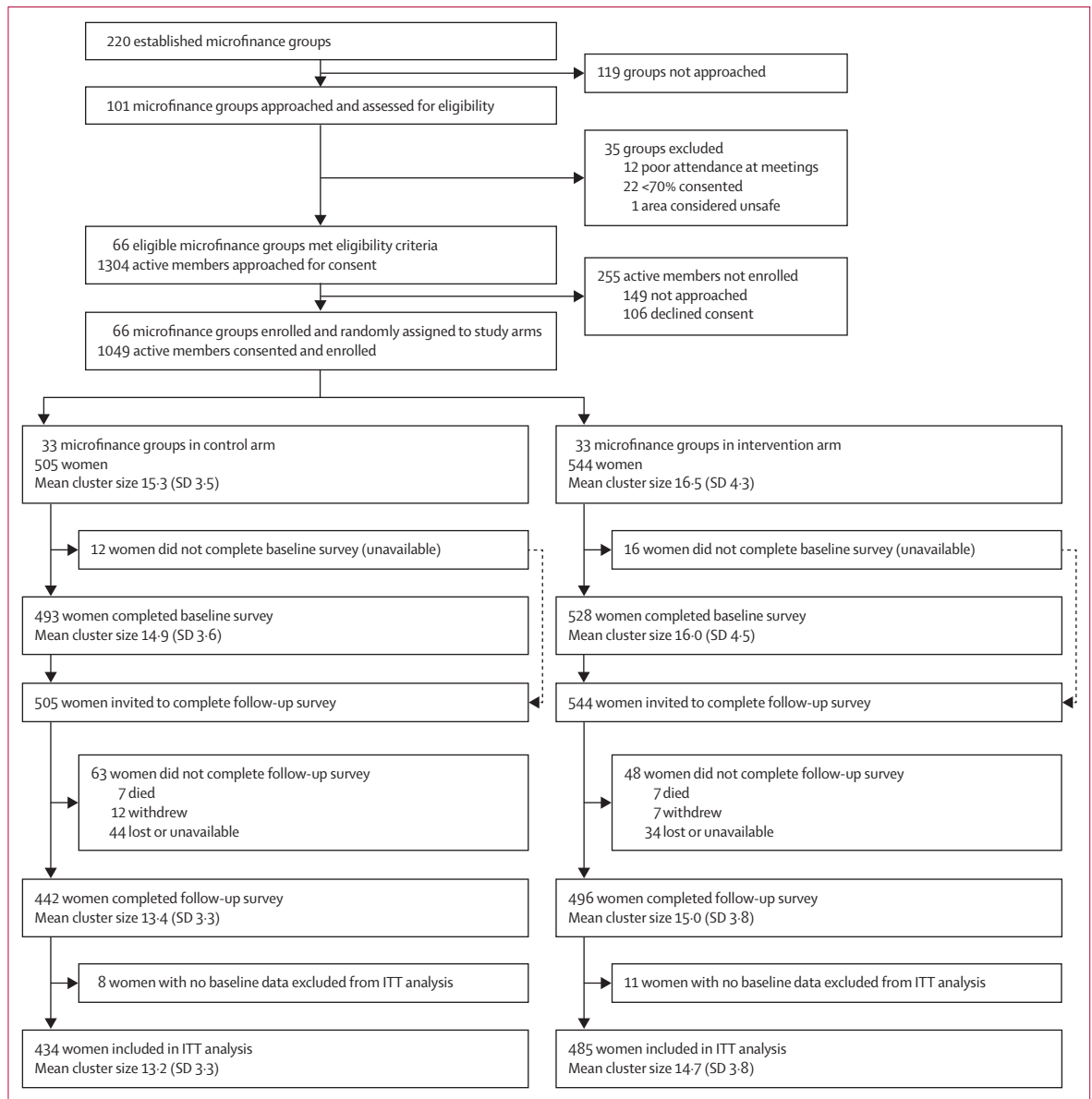


Figure 3: Trial profile
ITT=intention-to-treat.

randomisation (ie, 24 months after intervention). Since we hypothesised that the intervention might not affect all types of intimate partner violence in the same way, or to the same degree, past-year physical intimate partner violence, sexual intimate partner violence, and emotional abuse were also considered separately as secondary outcomes. Other secondary outcomes were intimate partner violence-related attitudes and beliefs, and past-year disclosure of intimate partner violence among women who reported past-year experience of physical or sexual intimate partner violence.

The outcome assessments were originally planned at 17 months after randomisation (ie, 12 months after

intervention); however, this timeframe was extended to 29 months after randomisation (ie, 24 months after intervention) to allow comparability with results from the IMAGE study.

Statistical analysis

The sample size calculation assumed an estimated prevalence of past-year physical or sexual intimate partner violence, or both, of 30% in the comparison arm.^{13,14} It was calculated that a sample size of 33 microfinance loan groups per trial arm with an average of 20 participants per group (allowing for 10% loss to follow-up based on previous work) would

provide 80% power to detect a 30% relative reduction (9% absolute reduction) in past-year physical or sexual intimate partner violence, and 90% power to detect a 34% relative reduction, assuming an intra-cluster correlation of 0.02.

Baseline and outcome data were recorded directly onto tablet computers with in-built checks to minimise missing or erroneous data. Data were uploaded daily to a secure database and checked by the data manager. Data queries were sent to the field team leader to be resolved with the data collectors. Data analysis was done using SAS (version 9.1), following a prespecified analysis plan (appendix pp 7–11), by analysts who were masked to group allocation. The primary analysis was done following the intention-to-treat principle, whereby participants were analysed according to the trial arm to which they were randomly allocated, irrespective of whether or not they participated in the intervention or control activities. All participants who provided both baseline and follow-up data were included in the analysis to allow for adjustment of baseline characteristics. The crude intervention effect, odds ratio (OR) with 95% CI, for each outcome was estimated using a logistic regression model with random intercepts for microfinance group (unit of randomisation) to account for the clustered nature of the data. Adjusted ORs (aORs) were estimated in the same way, except the models included terms for age (modelled as a linear effect), baseline measure of the respective outcome, and education (secondary or higher vs primary or none). There was no adjustment for multiplicity.

In a real-world setting, it is inevitable that not all women will be able to attend every session. The research team (comprising researchers and intervention developers and implementers) considered participation in seven or more sessions would constitute a good attendance for the intervention. We therefore did a per-protocol analysis by restricting the analysis to women in the intervention arm who participated in seven or more intervention sessions, and propensity score-matched women in the control arm. Dose-response effects on attitudinal outcomes were further assessed by adding number of intervention sessions (as a linear term) to the logistic regression model used for the primary analysis.

The robustness of the primary analysis was further examined through sensitivity analyses as follows: adding a random intercepts term for interviewer to control for possible heterogeneity in outcome reporting between interviewers; including all participants who completed the baseline questionnaire, using multiple imputation to simulate missing endline data; and using Complier Average Causal Effect estimates²² to assess the explanatory effects of the intervention among women attending seven or more sessions, and to examine the robustness of the findings from the propensity score analysis. Since the trial commenced, more sophisticated measures of emotional or psychological abuse have been proposed.

	Intervention arm	Control arm
Microfinance groups		
Number of groups	33	33
Group size	20 (16–24)	19 (17–23)
Percentage of group members who received first BRAC loan before 2014	75% (18)	80% (13)
Loan size of members (Tanzanian shillings)*	622 727 (162 062)	720 455 (202 470)
Individual trial participants†		
Number of participants	485	434
Age (years)	39.2 (9.4)	40.1 (9.5)
Marital status		
Married	353 (73%)	322 (74%)
Divorced or separated	69 (14%)	65 (15%)
Widowed	50 (10%)	37 (9%)
Never married	13 (3%)	10 (2%)
Had ≥1 partner in past year	426 (88%)	379 (87%)
Highest level of education		
None or incomplete primary	81 (17%)	50 (12%)
Completed primary	325 (67%)	266 (61%)
Secondary or higher	79 (16%)	118 (27%)
Partner's age (years)	45.6 (10.6)	46.8 (10.4)
Partner's education		
None or incomplete primary	37 (8%)	12 (3%)
Completed primary	253 (52%)	227 (52%)
Secondary or higher	178 (37%)	180 (41%)
Not known	17 (4%)	15 (3%)
Number of children (<18 years)		
None	31 (6%)	28 (6%)
1–2	162 (33%)	139 (32%)
3–4	189 (39%)	179 (41%)
≥5	103 (21%)	88 (20%)
Reported physical or sexual intimate partner violence		
Ever	303 (62%)	258 (59%)
Past year	138 (28%)	104 (24%)
Reported physical intimate partner violence		
Ever	261 (54%)	226 (52%)
Past year	94 (19%)	78 (18%)
Reported sexual intimate partner violence		
Ever	190 (39%)	135 (31%)
Past year	96 (20%)	55 (13%)
Reported emotional abuse		
Ever	339 (70%)	292 (67%)
Past year	207 (43%)	159 (37%)
Reported attitudes accepting of intimate partner violence	287 (59%)	217 (50%)
Reported belief that a woman should tolerate violence in order to keep the family together	423 (87%)	381 (88%)
Reported belief that intimate partner violence is a private matter and others should not intervene	61 (13%)	43 (10%)
Disclosed intimate partner violence in past year (among those reporting physical or sexual intimate partner violence in past year)	98/138 (71%)	75/104 (72%)
Data are median (IQR), mean (SD), n (%), or n/N (%). *Mean of all the group-level medians; 2305 Tanzanian shillings is equal to US\$1. †Microfinance group members who consented to take part in the trial.		
Table 1: Baseline characteristics of enrolled microfinance groups and group members enrolled into the trial who provided both baseline and follow-up data		

We therefore did a sensitivity analysis with a measure of high intensity psychological abuse²³ in addition to the original prespecified measure (panel).

This trial is registered with ClinicalTrials.gov, number NCT02592252.

Role of funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The lead authors, two statisticians (CHH and TA), and senior author had full access to all the data in the study and were responsible for the final review of the manuscript. All authors approved the final version of the manuscript before submission for publication.

Results

Between September, 2014, and June, 2015, we approached 101 (46%) of 220 established microfinance groups in the study area. Of these 101, 66 (65%) groups fulfilled the trial eligibility criteria and were enrolled (appendix p 12). In the 66 groups, there were 1304 active members, of

whom 1049 (80%) women consented to take part and were randomly assigned to their groups (544 in the intervention arm and 505 in the control arm). Before randomisation, 1021 (97%) of 1049 women completed the baseline interview. Between May, 2017, and January, 2018, 485 (89%) of 544 women in the intervention arm and 434 (86%) of 505 women in the control arm completed the follow-up interview and were included in the intention-to-treat analysis (figure 3).

The median age of women was 39 years (IQR 33–46).¹⁷ All participants reported having had a partner (ie, regular or casual) at some point in their lives, with most married or living as married at baseline (675 [73%] of 919). 591 (64%) of 919 women had completed primary education. Table 1 shows the baseline characteristics of both the microfinance groups and trial participants. Although characteristics of the microfinance groups and individual trial participants in the two trial arms were largely similar, a slightly higher proportion of women in the control arm than in the intervention arm reported receiving their first BRAC loan before 2014 (80% vs 75%). In addition, women in the control arm were more likely

	Intervention arm	Control arm	Crude OR* (95% CI)	p value	Adjusted OR† (95% CI)	p value
Intention-to-treat analysis						
Number of participants	485	434
Physical or sexual intimate partner violence, or both	112 (23%)	119 (27%)	0.79 (0.56-1.13)	0.189	0.69 (0.47-1.01)	0.056
Physical intimate partner violence	68 (14%)	82 (19%)	0.69 (0.45-1.07)	0.093	0.64 (0.41-0.99)	0.043
Sexual intimate partner violence	80 (16%)	74 (17%)	0.95 (0.62-1.45)	0.807	0.80 (0.51-1.25)	0.316
Emotional intimate partner violence	183 (38%)	154 (35%)	1.10 (0.84-1.44)	0.480	0.98 (0.73-1.32)	0.910
Attitudes accepting of intimate partner violence	215 (44%)	243 (56%)	0.63 (0.48-0.81)	0.0004	0.45 (0.34-0.61)	<0.0001
Believes a woman should tolerate violence in order to keep the family together	79 (16%)	93 (21%)	0.71 (0.48-1.06)	0.092	0.68 (0.45-1.01)	0.055
Believes intimate partner violence is a private matter and others should not intervene	32 (7%)	51 (12%)	0.53 (0.33-0.84)	0.007	0.51 (0.32-0.81)	0.005
Disclosed intimate partner violence in past year (among those experiencing physical or sexual intimate partner violence in past year)	88/112 (79%)	84/119 (71%)	1.53 (0.84-2.78)	0.166	1.41 (0.74-2.72)	0.293
Propensity score-matched per-protocol analysis						
Number of participants	332	332
Physical or sexual intimate partner violence	75 (23%)	93 (28%)	0.74 (0.49-1.13)	0.163	0.64 (0.42-0.98)	0.039
Physical intimate partner violence	47 (14%)	66 (20%)	0.65 (0.40-1.07)	0.088	0.58 (0.35-0.94)	0.028
Sexual intimate partner violence	52 (16%)	55 (17%)	0.91 (0.54-1.55)	0.739	0.80 (0.47-1.37)	0.423
Emotional intimate partner violence	118 (36%)	115 (35%)	1.04 (0.76-1.43)	0.807	0.88 (0.62-1.26)	0.499
Attitudes accepting of intimate partner violence	131 (39%)	187 (56%)	0.51 (0.37-0.69)	<0.0001	0.34 (0.24-0.49)	<0.0001
Believes a woman should tolerate violence in order to keep the family together	40 (12%)	77 (23%)	0.45 (0.28-0.72)	0.001	0.42 (0.26-0.67)	0.0002
Believes intimate partner violence is a private matter and others should not intervene	19 (6%)	43 (13%)	0.40 (0.22-0.74)	0.004	0.39 (0.21-0.74)	0.004
Disclosed intimate partner violence in past year (among those experiencing physical or sexual intimate partner violence in past year)	58/75 (77%)	67/93 (72%)	1.32 (0.65-2.68)	0.435	1.23 (0.58-2.61)	0.596
Data are n (%) or n/N (%), unless otherwise specified. OR=odds ratio. *ORs estimated using logistic regression models with random intercepts for microfinance group. †Models to estimate adjusted ORs included terms for age (linear term), baseline measure of the respective outcome, and education (secondary or higher vs primary or none).						
Table 2: Estimates of intervention effect on outcome indicators from intention-to-treat and per-protocol analyses						

to report secondary or higher education than those in the intervention arm (27% vs 16%), and there were slight differences in reported intimate partner violence, with women in the intervention arm more likely to have experienced past-year sexual intimate partner violence than those in the control arm (20% vs 13%). The intra-cluster correlation for baseline past-year physical or sexual intimate partner violence, or both, was 0.04 (95% CI 0.01–0.14). Of the 485 women in the intervention arm, 332 (68%) participated in at least seven of ten intervention sessions.

Table 2 summarises the results of the intention-to-treat and per-protocol analyses. At follow-up, past-year physical or sexual intimate partner violence, or both, were reported by 112 (23%) of 485 women in the intervention arm and 119 (27%) of 434 in the control arm. The aOR was 0.69 (95% CI 0.47–1.01; $p=0.056$), equivalent to an approximate-adjusted risk reduction of 25%. The effect was strongest for physical intimate partner violence (aOR 0.64, 95% CI 0.41–0.99; $p=0.043$), with an approximate-adjusted risk reduction of 32%. There was inadequate evidence for an effect on sexual intimate partner violence (aOR 0.80, 95% CI 0.51–1.25; $p=0.316$) or on emotional abuse (0.98, 0.73–1.32; $p=0.910$). Women in the intervention arm were considerably less likely than their counterparts in the control arm to report attitudes accepting of intimate partner violence (aOR 0.45, 95% CI 0.34–0.61; $p<0.0001$) or the belief that intimate partner violence is a private matter (0.51, 0.32–0.81; $p=0.005$). Additionally, women in the intervention arm were also less likely than those in the control arm to believe that a woman should tolerate violence in order to keep her family together (aOR 0.68, 95% CI 0.45–1.01; $p=0.055$). Among the women reporting past-year physical or sexual intimate partner violence, or both, results are suggestive of a small increase in odds of disclosure of intimate partner violence in the intervention arm, however, inference is severely limited by the restricted sample size for this outcome. Measures of effect were not affected by inclusion of a random intercepts term for interviewer (appendix p 13), or when multiple imputation was used to impute missing outcome data for participants who only completed the baseline questionnaire (appendix p 13). There was also no evidence of an effect for emotional abuse using the high intensity measure (aOR 0.97, 95% CI 0.63–1.51).

Intervention effects were greater among women who participated in seven or more intervention sessions. When the analysis was restricted to this high-attendance group and propensity score-matched women in the control arm, the effect on the primary outcome was marginally stronger (aOR 0.64, 95% CI 0.42–0.98; $p=0.039$), and the effect on attitudes related to intimate partner violence was considerably larger (0.34, 0.24–0.49; $p<0.0001$; table 2). The pattern of a stronger intervention effect among women participating in seven or more sessions was confirmed in our Complier Average

Causal Effect analysis (posterior mean aOR 0.57, 95% posterior interval 0.33–0.97; appendix p 13). Furthermore, we found a dose–response relationship between number of sessions attended and each of the attitude outcomes (appendix pp 14, 15). The odds of reporting attitudes accepting of intimate partner violence decreased by about 10% for each additional intervention session attended (appendix p 16).

During the trial, 31 women requested assistance from the trial team in seeking help and support for ongoing intimate partner violence and related issues. There were no reports that participation in the trial had led to new episodes of violence or worsening of ongoing violence and abuse.

Discussion

This trial has shown that over a 2-year period, reported past-year physical or sexual intimate partner violence, or both, was reduced among women who participated in the MAISHA intervention. The effect was greater for past-year physical intimate partner violence, which was reduced by a third. However, evidence of an effect on past-year sexual intimate partner violence was limited. Women in the intervention arm were much less likely than those in the control arm to express attitudes accepting of intimate partner violence, express beliefs that intimate partner violence is a private matter, or that a woman should tolerate intimate partner violence in order to keep her family together.

The observed reduction in reported past-year physical intimate partner violence adds to evidence from the IMAGE study that a social empowerment intervention combined with economic empowerment can be effective in reducing women's experience of intimate partner violence. In the IMAGE study,¹¹ women receiving microfinance combined with a participatory gender and HIV curriculum experienced a 55% reduction in relative risk of physical or sexual intimate partner violence compared with women receiving no intervention. However, since the trial tested a combined intervention, questions remained as to what extent each component contributed to the observed effects.¹² The results of MAISHA suggest that the addition of a social empowerment intervention to existing microfinance programmes can lead to considerable reductions in physical intimate partner violence over and above those that might result from microfinance alone.

We cannot comment on whether the results of this trial are generalisable to women not engaged in formal group-based microfinance. Studies have suggested that microfinance can reduce intimate partner violence through economic empowerment of women, which in turn, leads to greater self-esteem and self-confidence, wider social networks, and household decision-making power.^{24,25} However, other studies suggest that microfinance can potentially increase intimate partner violence by challenging established gender norms and male authority.^{24,25} It is

possible that synergies between the MAISHA intervention and economic empowerment are necessary to produce the effects we observed,²⁵ which corresponds with the finding from a review indicating positive outcomes when economic strengthening and gender transformative interventions are combined.¹⁰ To understand whether the MAISHA intervention could have the same effect among women not engaged in a formal microfinance scheme, a second, linked cluster randomised controlled trial is currently ongoing in Mwanza city among newly formed groups of women not engaged in formal microfinance, comparing groups receiving the MAISHA intervention with wait-list comparison (ie, control) groups.

The MAISHA intervention had a considerable effect on women's attitudes and beliefs about violence. Social desirability bias is possible; however, anecdotal evidence suggests increased bystander action as a result of changes in attitudes and beliefs among participants. Some have described mobilising their neighbours to address violence, either by confronting perpetrators directly, or reporting violent behaviour to the police or local leaders. Further analyses of quantitative and qualitative data will explore the pathways by which changes in attitudes and beliefs might have had an effect on intimate partner violence.

Although MAISHA was associated with marked reductions in physical intimate partner violence, effects on sexual intimate partner violence were more limited. The SASA! intervention in Uganda also led to relatively smaller reductions in sexual intimate partner violence compared with physical intimate partner violence,¹⁹ a pattern that was hypothesised from the outset of the study.²⁶ Although the Safe Homes and Respect for Everyone (SHARE) intervention, combining intimate partner violence prevention with HIV services in Uganda, found evidence for a reduction in past-year sexual intimate partner violence, the effect size was relatively small with a prevalence rate ratio of 0.80 (95% CI 0.67–0.97).²⁰ We did not assess acceptance of sexual intimate partner violence among trial participants but social norms supporting sexual entitlement within marriage are deeply entrenched in Tanzania, and some participants commented during the trial that refusal to have sex with a partner can trigger physical violence.

Women in violent relationships often experience pervasive emotional abuse compared with more discrete acts of physical and sexual violence.²⁷ We found no evidence of an intervention effect on emotional abuse, even when we used a recently published high-intensity emotional aggression measure.²³ Similarly, there was no evidence for an effect on emotional abuse from the SHARE intervention.²⁰ This finding is in contrast to SASA!, in which reductions in emotional abuse were observed across a range of measures.²⁸ Some have suggested that emotional abuse or controlling behaviour might provide an alternative outlet for a man who has stopped using physical or sexual violence.²⁸ However, we

found no evidence of increased emotional abuse. Even so, the overall prevalence was high, and although it frequently intersected with reports of physical and sexual violence, in some cases it was the only form of abuse reported.¹⁷ Recent evidence has shown a link between emotional abuse and mental ill-health among women, illustrating the need for greater attention to this more neglected form of intimate partner violence.²⁷

The MAISHA intervention might have enabled women to recognise, manage, and reduce their partner's use of physical violence but its small effect on sexual violence and emotional abuse suggests the need to engage more with men in addressing these forms of violence. During intervention activities and meetings to disseminate the trial results, participants commented on the need for men's participation in violence prevention activities. As part of the MAISHA trial, an intervention for men following a similar curriculum to *Wanawake Na Maisha* has been developed and piloted. Work is ongoing to learn more about how best to engage men with a view to informing future violence prevention interventions involving them. In addition, a cross-sectional survey of male partners of trial participants who agreed will explore men's knowledge and attitudes towards intimate partner violence, how these compare with those of women, and whether the intervention delivered to women has had any effect on their male partners.

The trial has some limitations. It is possible that the microfinance groups enrolled are not a representative sample of established formal microfinance loan groups in Mwanza city, although this limitation would affect the generalisability of the trial results rather than compromise the internal validity of the trial itself. Despite high consent and high retention rates, it is possible that women who did not consent to take part, or who were lost to follow-up differed from those included in the analysis. However, the sensitivity analysis using multiple imputation suggests that the effect of the intervention remained much the same when those lost to follow-up were included in the outcomes analysis.

Reporting bias is a concern, particularly as intimate partner violence is often under-reported. It is possible that exposure to the intervention might have increased sensitisation of women to intimate partner violence and related issues, and as a result, led to increased reports of violence among women in the intervention arm, resulting in an under-estimate of the effect size. Because of the nature of the intervention and the clustered trial design, it was not possible to mask the research team to group allocation. To reduce the risk of reporting bias, we assessed outcomes using questions that are standardised and widely used in violence research,¹³ with face-to-face interviews done by interviewers who had received extensive training.

Challenges to intervention delivery arose from the fact that intervention sessions were delivered just before or just after the weekly microfinance loan group meetings.

Delays in loan group meetings starting or ending meant that women sometimes missed sessions because they were anxious to get on with their business activities. If there were issues with loan repayments, general tensions within the group affected participation in sessions. Women who were unable to repay their loan often chose to stay away from loan group meetings, which meant that they then missed sessions. Even so, the intervention was successfully delivered, and two-thirds of women in the intervention arm participated in at least seven of the ten sessions, suggesting that it is acceptable to women. The per-protocol analysis showed that the effect of the intervention was strengthened among these women.

This trial has many strengths. Randomisation of microfinance groups ensured that there was no bias in programme placement. The trial was adequately powered with enrolment of a large sample of established formal microfinance loan groups, representing around one-third of established BRAC microfinance loan groups in the defined study area at the time. Retention rates were high for both arms (89% in the intervention arm vs 86% in the control arm). Data were analysed following the intention-to-treat principle and a prespecified analysis plan, with data analysts masked to trial allocation. Baseline data enabled us to adjust for baseline imbalances between the trial arms, according to the prespecified analysis plan. The mixed methods design of the trial, utilising quantitative and qualitative approaches, will allow a better understanding of the effect of the intervention and how it is experienced by participants. Data from the complementary longitudinal qualitative study will be invaluable in exploring women's experiences of the intervention and format, the process of change and potential reasons for its effect on different forms of violence and abuse, and variations in effect across groups or individual participants. An economic analysis will provide further data for the cost and cost-effectiveness of the intervention.

In summary, intimate partner violence is a major problem in Tanzania and many other sub-Saharan countries. The Tanzanian Government is committed to addressing this problem through its national plan of action to end violence against women.²⁹ This trial addresses the UN's Sustainable Development Goal 5 to eliminate all forms of violence and abuse against women and girls by adding to a growing body of evidence that violence can be prevented.^{11,19,20} It has shown that a relatively short intervention integrated into an existing economic empowerment platform can reduce past-year physical intimate partner violence. Given the high prevalence of intimate partner violence observed in this study and others,^{13–15,17} the MAISHA intervention has the potential to positively affect the lives of a large number of women in Tanzania and other similar high-risk settings.

Contributors

SK contributed to the trial design, provided methodological input and oversight of the trial, and co-wrote the first draft of the trial report.

SH provided methodological input, coordinated the trial, managed the trial teams with assistance from IK, and co-wrote the first draft of the trial report. GM and SL contributed to the trial design and provided methodological input and oversight of the qualitative study.

CHH provided methodological input and statistical support. CHH and TA did the statistical analysis with assistance from NM. GJM and FM led the field team responsible for recruitment of participants and data collection. RH setup and managed the data management systems. CW conceived the idea and design of the trial, and provided methodological input. All authors contributed to interpreting the data and writing the manuscript.

Declaration of interests

Following initiation of the trial, CW has been seconded to the UK Government Department for International Development as their Chief Scientific Advisor. Her ongoing role in this trial is in her academic capacity at the London School of Hygiene & Tropical Medicine. All other authors declare no competing interests.

Data sharing

Study data in this paper, including anonymised individual participant data, will be made available upon publication to members of the scientific and medical community for non-commercial use only. Requests should be made to the corresponding author. Data will be stored in Data Compass, the London School of Hygiene & Tropical Medicine's digital data repository.

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