



A cluster randomised controlled trial to evaluate the impact of a gender transformative intervention on intimate partner violence against women in newly formed neighbourhood groups in Tanzania

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ABSTRACT

Introduction Violence against women is a global public health concern; around a quarter of women will experience intimate partner physical or sexual violence during their lifetime. We assessed the impact of a gender transformative intervention for women designed to prevent intimate partner violence (IPV).

Methods We conducted a cluster randomised controlled trial in Mwanza city, Tanzania, among women in newly formed neighbourhood groups to evaluate a 10-session participatory intervention that aims to empower women, prevent IPV and promote healthy relationships. Following a baseline interview, groups were randomly assigned (1:1 ratio) to the intervention or control arm. An intention-to-treat analysis was conducted to assess the impact of the intervention on the main outcomes, assessed 24 months postintervention. These included past-year physical IPV and sexual IPV (primary); past-year emotional abuse; and acceptability and tolerance of IPV.

Results Between September 2015 and February 2017, 1265 women were recruited in 66 neighbourhoods and randomly allocated to intervention (n=627 women in 33 neighbourhoods) or control (n=638 women in 33 neighbourhoods). Assessment of outcomes was completed for 551 (88%) intervention and 575 (90%) control women. Among intervention women, 113 (21%) reported physical IPV compared with 117 (20%) control women (adjusted OR (aOR) 0.98, 95% CI 0.72 to 1.33, p=0.892), and 109 (20%) intervention women reported sexual IPV compared with 121 (21%) control women (aOR 0.98, 95% CI 0.72 to 1.32, p=0.881). Intervention women reported less emotional abuse (aOR 0.74, 95% CI 0.56 to 0.98, p=0.035), and were less likely to express attitudes accepting of IPV (aOR 0.49, 95% CI 0.36 to 0.66, p<0.001), and beliefs that IPV is a private matter (aOR 0.54, 95% CI 0.38 to 0.78, p=0.001), or should be tolerated (aOR 0.48, 95% CI 0.34 to 0.66, p<0.001).

Conclusion These results indicate that the intervention was effective in reducing emotional abuse and positively

Key questions

What is known already?

- Global estimates based on prevalence data from 2000 to 2018 indicate that around a quarter of women who have ever been in a relationship have experienced physical and/or sexual violence from a current or former intimate partner.
- There is a growing body of evidence from randomised controlled trials that interventions for women that combine social empowerment or gender transformative interventions with economic strengthening are effective in preventing intimate partner violence.
- A previous trial of the MAISHA gender transformative intervention, delivered to women in established microfinance groups, showed a positive impact on women's past-year experience of physical intimate partner violence and on their attitudes and beliefs about intimate partner violence.

What are the new findings?

- In this second trial of the MAISHA intervention, women living in the same neighbourhood were formed into groups to receive the intervention. There was a positive impact on women's attitudes and beliefs about violence, and on their past-year experience of emotional abuse from an intimate partner.
- Though there were anecdotal reports from intervention arm women of improvements in their relationships, the intervention did not lead to measurable reductions in their past-year experiences of physical or sexual intimate partner violence.

impacting attitudes and beliefs condoning IPV, but was not sufficient to reduce physical or sexual IPV.

Trial registration number NCT02592252.

Key questions

What do the new findings imply?

- ▶ This trial, combined with the first MAISHA trial, provides evidence that while a gender transformative intervention alone may not be sufficient to reduce physical or sexual intimate partner violence, the same intervention in the context of economic strengthening of women is effective in reducing physical violence.
- ▶ These findings add to mounting evidence that combining gender transformative interventions with economic strengthening programmes has a positive impact on intimate partner violence.

INTRODUCTION

Violence against women has been described by WHO as a 'global public health problem of epidemic proportions'.¹ The most common form of violence against women is intimate partner violence (IPV) with the most recent estimates from population surveys indicating that, worldwide, around a quarter of women have experienced physical and/or sexual violence from an intimate partner in their lifetime.² The negative impacts of IPV on physical and mental health are considerable for women and their families.^{1 3-5}

There is a growing body of rigorous evidence demonstrating that IPV is preventable.^{6 7} Much of this research has been conducted in sub-Saharan Africa,⁸ which is among the world regions with the highest rates of IPV.⁹ One of the first randomised controlled trials (RCTs) was the Intervention with Microfinance for AIDS and Gender Equity (IMAGE) trial, implemented in rural South Africa.¹⁰ The intervention combined group-based microfinance with a participatory gender and HIV training programme. In a cluster RCT IMAGE was shown to reduce women's past year experience of physical and/or sexual IPV by 55% over a 2-year period. In addition, levels of household poverty were significantly reduced, and participants were more empowered as evidenced by greater self-confidence, autonomy in decision making, and increased ability to challenge gender norms when compared with women in the control population.¹⁰

Population surveys have revealed high levels of IPV against women in Tanzania, with almost 30% of ever-partnered women having experienced physical and/or sexual IPV in the year prior to the survey.¹¹ Recent estimates from WHO indicate that violence remains high in Tanzania: 38% (95% uncertainty interval: 28%–50%) of ever-married or partnered women aged 15–49 years have experienced physical and/or sexual IPV in their lifetime, and 24% (95% uncertainty interval: 16%–35%) have experienced it in the past 12 months.² Effective prevention interventions are urgently needed to address this public health crisis. Because the IMAGE model was a combined microfinance-training intervention, it was difficult to know the extent to which the observed effect on IPV was attributable to the different components of the intervention. Inspired by the IMAGE study, we aimed to better understand the relative and combined effects

of economic and social empowerment interventions in Tanzania on women's experience of IPV. We previously reported the results of a trial investigating the effect of the MAISHA social empowerment group-based intervention on experiences of IPV among women taking part in a microfinance loan scheme. We found that the intervention was associated with a reduction in reported physical or sexual IPV, although the effect was greater for physical IPV.¹² In this second separate trial, we assessed the effect of the same intervention on experiences of IPV among women living in the same neighbourhood who were not engaged in a formal microfinance loan scheme.

METHODS

Trial design

We conducted a cluster RCT in Mwanza city, north-western Tanzania in close collaboration with local community leaders. The background, design and methods are described in detail elsewhere.¹³ The trial team worked with community leaders to identify suitable neighbourhoods across the city in which to form groups of women who would be eligible to participate in the trial. Once a potential neighbourhood had been identified, MAISHA team members worked with local leaders to identify and visit households in the neighbourhood in order to invite potentially eligible women to attend information meetings. Women who were interested in taking part were invited to attend subsequent meetings to obtain detailed information about the trial, including the overall aim and objectives, eligibility criteria and trial procedures.¹³

Women were eligible for inclusion if they were aged 20–50 years, resident in Mwanza for 2 years or more, not a member of formal microfinance loan group scheme in the past 12 months, and were fluent in Swahili. We excluded women who were formally employed so the population would be more comparable with the previous MAISHA CRT01 trial population,¹² and be available to attend intervention sessions. Research staff met with potentially eligible women to go through the participant information sheet explaining the purpose of the trial and the procedures. Women who demonstrated comprehension of the trial procedures and agreed to take part were invited to sign the consent form (online supplemental material 1). Within each neighbourhood, we aimed to recruit around 15–20 women.

Safety

The trial was designed following WHO recommendations on researching violence against women.¹⁴ To ensure women's safety, trained staff interviewed participants in private, and maintained regular contact with them throughout the trial. A referral system was established to assist women who reported experiencing violence to access appropriate services and support. Information about local support services was provided to all participants irrespective of whether they reported experiencing violence.

Randomisation and masking

Over 18 months, women in 66 neighbourhoods were recruited and the neighbourhood clusters then randomised in blocks of six as they were enrolled into the trial. For each block of six neighbourhood clusters, community randomisation ceremonies were conducted as a two-stage process that was both participatory and transparent involving the research team and representatives nominated by members from each of the neighbourhood clusters to be randomised. First, representatives from each of the six clusters were randomly divided equally into two sets (A and B). This was done by each representative drawing a folded sheet of paper (with A or B written on it) from a box. Second, one of the representatives from either A or B was asked to call (heads or tails) for her set to be allocated to immediate intervention. A trial team member then tossed a coin to randomly allocate each set of three clusters to either the intervention or to control (to receive the intervention after the trial). It was not possible to mask participants or the research team involved in day-to-day operations and delivery of the intervention.

Procedures

The trial timeline is outlined in [figure 1](#). Prior to randomisation, we conducted a face-to-face interview with each participant using a structured questionnaire adapted from the WHO Violence Against Women instrument,¹¹ which has also been widely used in Demographic and Health Surveys and other IPV prevention intervention trials.^{10 15 16} The questionnaire was translated into Swahili (the national language) and independently back-translated into English for validation. Interviews were conducted in private by female interviewers trained in interviewing techniques, gender issues, violence and ethical issues related to research on IPV.¹⁴

Women in neighbourhoods allocated to the intervention arm participated as a group in the 10-session MAISHA intervention following the Wanawake na Maisha (which means ‘women and life’ in Swahili) curriculum, which was developed by EngenderHealth (an international non-profit organisation focussing on gender equity and reproductive health—www.engenderhealth.org) in collaboration with the research team, drawing on other published curricula, including Sisters for Life from IMAGE. The MAISHA intervention was designed to be participatory and reflective, and aimed to empower women, prevent IPV, and promote healthy relationships by: increasing knowledge and awareness (eg, of the consequences of normative attitudes to gender and IPV); developing relationship skills (eg, communication and conflict resolution); and improving group dynamics and stability (eg, increased peer support and social capital).

The 10-session MAISHA intervention (outlined in [figure 2](#)) was delivered to the 33 intervention arm groups on alternate weeks over a 20-week period. Each session lasted between 1.5 and 2 hours. Venues were selected to be convenient to participants, with sessions generally

taking place at the group leader’s house or in a quiet area of a local café or guesthouse. Sessions were 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, allowing them 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. Intervention delivery was monitored by the trial coordinator and senior research team members. Curriculum facilitators maintained session attendance registers to monitor attendance and ensure that sessions were attended by intervention arm women only, thereby minimising the potential for contamination.

The curriculum facilitators had no contact with women in neighbourhoods allocated to the control arm. However, to minimise the risk of attrition bias, the research team maintained regular contact with both intervention and control arm women during the 2-year period between the end of the intervention and assessment of outcomes. The impact of the intervention was assessed through interviews conducted 29 months postrandomisation with both trial arms (24 months after groups completed intervention activities). Interviews were conducted 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 primary outcomes were women’s reports of past year physical IPV and past-year sexual IPV. The original primary outcome was a composite of past year physical and sexual IPV. However, this was revised in light of the results of MAISHA CRT01¹² and evidence from other violence prevention trials^{15 16} indicating limited impact on sexual IPV, a pattern that was hypothesised from the outset of the SASA! trial.¹⁷ It was decided, therefore, that reported past year experience of physical IPV and sexual IPV should be evaluated as separate primary outcomes at 29 months postrandomisation (24 months postintervention). A favourable opinion for this amendment was received from the ethics committee before the end of follow-up and prior to analysis of data. Secondary outcomes were emotional abuse, three measures of IPV related attitudes and beliefs, and past year disclosure of IPV among women who reported past year experience of physical/sexual IPV. Details of questionnaire items used to construct the outcomes are presented in [Table 1](#).

Sample size

It was calculated that a sample size of 33 neighbourhood clusters per trial arm with an average of 20 participants per cluster (allowing for 10% loss to follow-up) would provide 80% power to detect a reduction of 33% in past year IPV, and 90% power to detect a reduction of 38%, assuming an intracluster correlation (ICC) of 0.035. Even

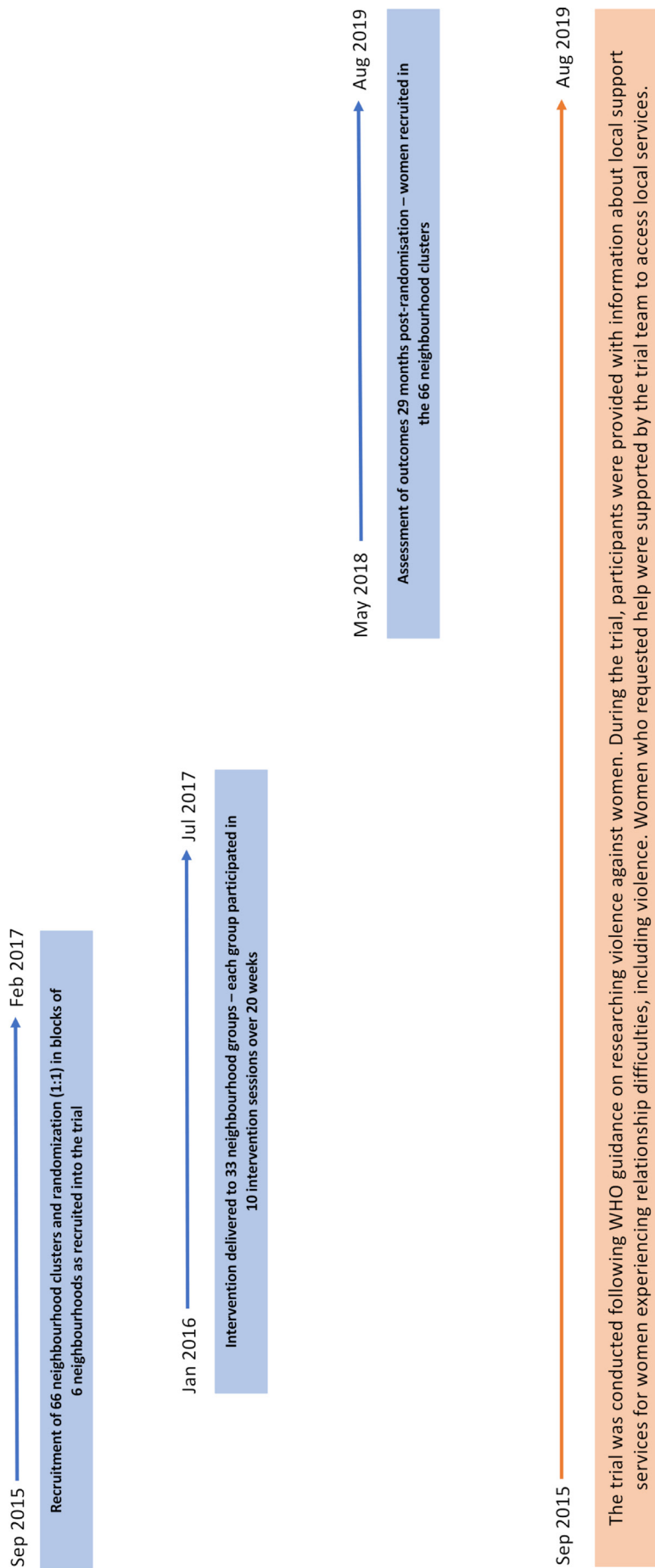


Figure 1 Trial timeline.

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.

<p>1. Introduction and understanding gender</p> <ul style="list-style-type: none"> • What is meant by “gender” and “sex”? • How can gender norms affect women’s health and well-being? 	<p>2. Act like a man, act like a woman</p> <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? 	<p>3. Healthy and unhealthy relationships</p> <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? 	<p>4. Power in relationships</p> <ul style="list-style-type: none"> • What is it like to have power (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 and how can this be obtained?
<p>5. Negotiating men’s and women’s roles inside and outside the home</p> <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 well-being? • Is the division of labour between men and women in the home fair, healthy, or “natural”? 	<p>6. Communicating assertively with your partner</p> <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? 	<p>7. What is violence?</p> <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, communities? • What are the alternatives to violence? 	<p>8. Setting personal boundaries</p> <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?
<p>9. Non-violent ways to resolve conflict</p> <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? 	<p>10. Empowering change</p> <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? 	<p>The intervention ends with a candle ceremony</p> <p><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 	



Figure 2 MAISHA intervention—Wanawake Na Maisha curriculum.

Table 1 Questions used to construct primary and secondary outcomes assessed at 29 months postrandomisation (24 months postintervention)

Outcome	Questions
Physical IPV (primary) (yes/no)	Reported that her current or any other partner has done <u>at least one</u> of the following things to her in the past 12 months: <ul style="list-style-type: none"> ▶ Slapped her or thrown something at her that could hurt her. ▶ Pushed her or shoved her or pulled her hair. ▶ Hit her with his fist or something else that could hurt her. ▶ Kicked her, dragged her 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 IPV (primary) (yes/no)	Reported that <u>at least one</u> of the following things has happened to her in the past 12 months: <ul style="list-style-type: none"> ▶ 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.
Emotional abuse* (yes/no)	Reported that her current or any other partner has done <u>at least one</u> of the following things to her in the past 12 months: <ul style="list-style-type: none"> ▶ 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, by yelling and smashing things). ▶ Verbally threatened to hurt her or someone she cares about.
Disclosure of IPV (among women who physical and/or sexual IPV in the past 12 months) (yes/no)	Reported that she has told someone within the past 12 months about her partner's behaviour (violence/abuse) towards her.
Attitudes accepting of IPV (yes/no)	Reported that she 'strongly agrees' or 'agrees' that a man has good reason to hit his wife in <u>at least one</u> of the following scenarios: <ul style="list-style-type: none"> ▶ 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 IPV 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.
IPV, intimate partner violence.

with an ICC of 0.05, the trial would have 80% power to detect a reduction in past year physical IPV of 35%.

Data management and statistical analyses

All data collected at baseline and at follow-up were recorded directly onto tablet computers with in-built checks to minimise missing or erroneous data. At the end of each day, data were uploaded from the tablet computers 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 performed using STATA V.16 following a prespecified analysis plan (online supplemental material 1), by analysts who were blind to cluster allocation. The primary analysis was conducted following the intention-to-treat (ITT) 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 neighbourhood cluster (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/higher vs primary/none).

In a real-world setting, it is inevitable that participants will not be able to attend every session. As for the previous MAISHA trial, we considered attendance at seven or more sessions would constitute a good “dose” of the intervention. We, therefore, performed a per-protocol analysis in which we restricted the analysis to intervention arm women who attended seven or more intervention sessions, and propensity score matched control arm women. Dose response effects on attitudinal outcomes were further explored by adding number of intervention sessions (as a linear term) to the logistic regression model used for the primary analysis.

We also conducted several sensitivity analyses to assess the robustness of the primary analysis: (1) adding a random intercepts term for interviewer to control for possible heterogeneity in outcome reporting between interviewers; and (2) including all participants who completed the baseline questionnaire, using multiple imputation to simulate missing endline data. Since the trial commenced, more sophisticated measures of emotional/psychological abuse have been proposed. We, therefore, conducted a sensitivity analysis with a measure of ‘high intensity psychological abuse’¹⁸ in addition to the original prespecified measure (table 1).

Changes to the protocol

There were three amendments to the trial protocol described in detail elsewhere.¹³ Briefly, these were: (1) outcome assessments, originally planned at 17 months postrandomisation (12 months postintervention), were extended to 29 months postrandomisation (24 months postintervention) to allow comparability with the IMAGE trial results; (2) the original trial design was to invite male partners of trial participants to participate in a similar intervention designed for men. In light of poor accrual and poor participation in the intervention by enrolled men, the trial design was revised to include only women; and (3) the primary outcome was changed as previously described.

Participant and public involvement

The design of the MAISHA study was inspired by IMAGE and aimed to address questions raised by the trial in South Africa. Although there was not specific public involvement in development of the research question and outcomes, discussions were held with local community leaders and representatives about the purpose of the

study. Throughout the trial, the research team worked in collaboration with local community leaders to identify neighbourhoods across the city in which to form groups. Within each neighbourhood, the research team worked closely with local leaders to identify and invite women to local community information meetings about the study. The process of randomisation was a participatory process that involved participant representatives to ensure transparency in allocation of neighbourhoods to each arm of the trial.

Community advisory committees were established comprising local leaders, religious leaders, trial participants and other relevant stakeholders. These committees met regularly to facilitate effective communication between the research team and study communities, and to ensure that any concerns from members of the community were addressed promptly. The COVID-19 pandemic has impacted on dissemination activities, however the MAISHA team continues to work with the community advisory committees on plans to safely disseminate the trial results to participants and stakeholders in Tanzania.

RESULTS

Between September 2015 and February 2017, we identified 81 neighbourhoods and sought approval from local leaders to conduct research activities. Research activities were discontinued in 15 neighbourhoods when it became apparent that high numbers of women were members of formal microfinance loan schemes ($n=12$ neighbourhoods) or there were insufficient numbers of women who wished to take part ($n=3$ neighbourhoods). Across the remaining 66 neighbourhoods, 1912 women attended the information meetings. Of these, 1478 expressed interest in participating and were assessed for eligibility, of whom 1265 were ultimately enrolled (figure 3). A baseline interview was completed prior to randomisation by 1248 (99%) women. Between May 2018 and August 2019, 551 (88%) women in the intervention arm and 575 (90%) women in the control arm also completed the follow-up interview and were included in the ITT analysis (figure 3). There was no difference in baseline characteristics between women included in the ITT and those lost to follow-up.

Table 2A shows the baseline characteristics of participants by trial arm. The mean age of women was similar in both arms, around 33 years. Almost all participants ($n=1123$, 99.8%) reported having had a partner (regular or casual) at some point in their lives, with most married/living as married at baseline (80%–81%). The two arms were broadly similar, although there was a slight difference in education, with control arm women more likely to have attended secondary or higher education (22% vs 19%). In addition, control arm women reported higher median monthly income compared with intervention arm women (table 2A). Table 2B shows participants’ baseline reports of IPV and attitudes by trial arm. At baseline, control arm women were more likely to have reported

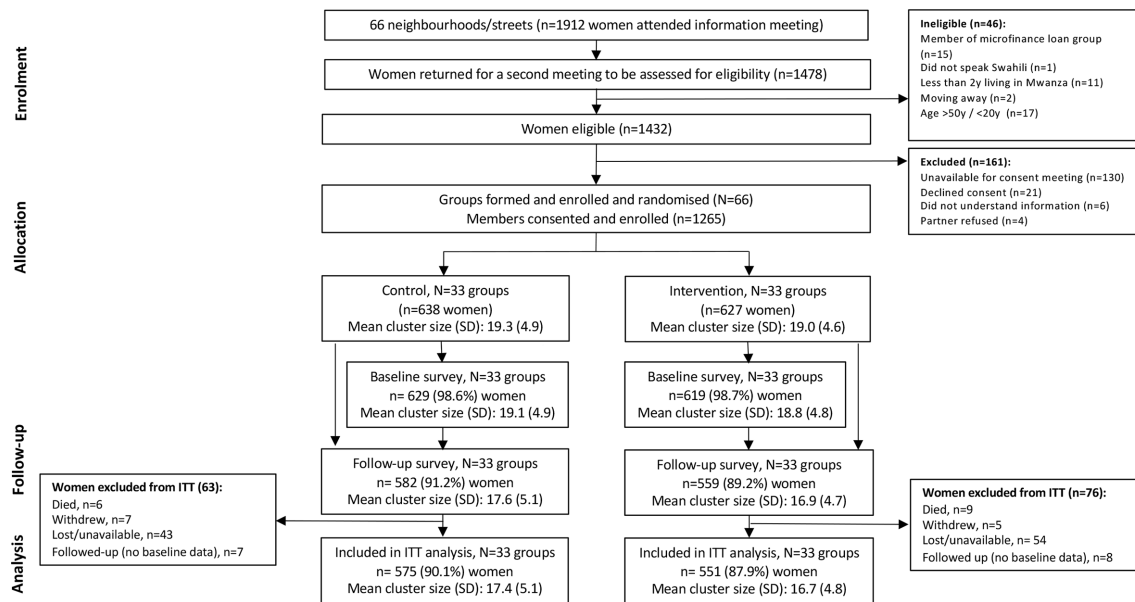


Figure 3 Trial profile. ITT, intention-to-treat.

past year sexual IPV (23% vs 19%) but were less likely to have attitudes accepting of IPV compared with intervention arm women (51% vs 58%) (table 2B). The ICC for baseline past year physical IPV was 0.0230 (SE 0.0211) and for past year sexual IPV 0.0001 (SE 0.0172).

Of the 551 intervention women, 85% (n=466) participated in at least seven of the 10 intervention sessions. In Table 3A, we present the results of the ITT analyses. At follow-up, past year physical IPV was reported by 21% of intervention arm women and 20% of control arm women. The aOR was 0.98 (95% CI 0.72 to 1.33, p=0.892). In addition, past year sexual IPV was reported by 20% of intervention arm women and 21% of control arm women. The aOR was 0.98 (95% CI 0.72 to 1.32, p=0.881). With respect to secondary outcomes, there was evidence of an impact on past year emotional abuse, which was reported by 39% of intervention arm women compared with 45% of control arm women (aOR 0.74, 95% CI 0.56 to 0.98, p=0.035). Furthermore, there was also evidence of impact on attitudes accepting of IPV (aOR 0.49, 95% CI 0.36 to 0.66, p<0.001), the belief that a woman should tolerate violence in order to keep her family together (aOR 0.48, 95% CI 0.34 to 0.66, p<0.001), and the belief that IPV is private matter and others should not intervene (aOR 0.54, 95% CI 0.38 to 0.78, p=0.001). Among the women reporting past year physical or sexual IPV, results are suggestive of decrease in odds of disclosure of IPV in the intervention arm, however, the CI is wide, and inference is severely limited by the restricted sample size for this outcome (table 3A).

Measures of effect were not affected by inclusion of a random intercepts term for interviewer (online supplemental table S1), or when multiple imputation was used to impute missing outcome data for participants who only completed the baseline questionnaire (online supplemental table S2). In contrast to when the prespecified measure of emotional abuse was used, there was

less evidence of an impact on emotional abuse using the ‘high intensity’ measure (aOR 0.79, 95% CI 0.55 to 1.12).

As with the ITT analysis, there was no impact on the primary outcomes when the analysis was restricted to women who participated in seven or more sessions and propensity scored matched controls (per-protocol analysis, Table 3B). While intervention impacts on the attitudinal outcomes were similar in this ‘high-dose’ group to those observed in the ITT analysis, the effect on emotional abuse was slightly stronger in the high dose group (aOR of 0.65, 95% CI 0.48 to 0.87, p=0.004), (table 3B). We found no evidence of a dose response effect on attitudinal outcomes among intervention arm women who attended one or more sessions (online supplemental figures S1-3 and table S3).

There were no reports that participation in the trial had led to new episodes of violence or worsening of ongoing violence and abuse. The trial team provided assistance to 43 women who wished to seek help and support for ongoing IPV and abuse.

DISCUSSION

In this trial, we found no evidence of an impact on either reported past year physical or sexual IPV among women who participated in the MAISHA intervention. There was, however, evidence of a reduction in past-year emotional abuse, and intervention women were much less likely to express attitudes accepting of IPV, express beliefs that IPV is a private matter, or that a woman should tolerate IPV in order to keep her family together.

The lack of an effect on past-year physical IPV is in contrast to the findings of a previous trial we conducted evaluating the impact of the MAISHA social empowerment intervention among women taking part in a formal microfinance scheme (MAISHA CRT01), where physical

Table 2A Baseline characteristics of participants included in the intention to treat analysis, by trial arm

Characteristic		Intervention (N=551) n (%)	Control (N=575) n (%)
Age (years)	Mean (SD) (range)	33.2 (8.1) (20–50)	33.0 (8.0)(18–50)
Marital status	Married	445 (81%)	461 (80%)
	Divorced/separated	52 (9%)	62 (11%)
	Widowed	26 (5%)	26 (5%)
	Never married	28 (5%)	26 (5%)
Partnered in past year		503 (91%)	527 (92%)
Highest level of education completed	None/incomplete primary	100 (18%)	114 (20%)
	Completed primary	344 (62%)	336 (58%)
	Attended secondary/higher	107 (19%)	125 (22%)
Partner's age (years)	Mean (SD) (range)	39.6 (9.6)(20–77)	39.4 (9.5)(22–68)
Partner's education	None/incomplete primary	45 (8%)	36 (6%)
	Completed primary	332 (60%)	331 (58%)
	Attended secondary or higher	153 (28%)	178 (31%)
	Unknown	19 (3%)	29 (5%)
No of children (<18 years)	None	24 (4%)	29 (5%)
	1–2	186 (34%)	234 (41%)
	3–4	225 (41%)	213 (37%)
	5+	116 (21%)	99 (17%)
Household experienced financial hardship in past year		385 (65%)	344 (60%)
Respondent worked for money during past 12 months		443 (80%)	461 (80%)
Respondent's monthly income (Tanzanian shillings)	Median (IQR)	88 000* (55 000 to 154 000)	110 000† (55 000 to 195 000)

*Equivalent to approximately US\$38 (US\$24 to US\$66).

†Equivalent to US\$47 (US\$24 to US\$84).

Table 2B Baseline reports of intimate partner violence, and attitudes and beliefs among ever-partnered participants included in the intention-to-treat analysis, by trial arm

Type of intimate partner violence/abuse	Intervention (N=549)* n (%)	Control (N=574) n (%)
Physical		
Ever	320 (58%)	325 (57%)
Past year	141 (26%)	140 (24%)
Sexual		
Ever	215 (39%)	239 (42%)
Past year	105 (19%)	130 (23%)
Emotional		
Ever	407 (74%)	406 (71%)
Past year	249 (45%)	252 (44%)
Disclosed violence in past year (among those experiencing physical/sexual IPV in past year)	138/187 (74%)	147/203 (72%)
Attitude/belief	(N=551)	(N=575)
Attitudes accepting of IPV	319 (58%)	296 (51%)
Believes a woman should tolerate violence in order to keep her family together	496 (90%)	497 (86%)
Believes IPV is a private matter and others should not intervene	64 (12%)	69 (12%)

*Three women (intervention n=2, control n=1) reported at baseline never being partnered, so excluded from the analysis.

IPV, intimate partner violence.

Table 3A Intention-to-treat analysis of intervention impact on primary and secondary outcomes reported 29 months postrandomisation among ever partnered women

Type of intimate partner violence/abuse	Intervention (n=550)* N (%)	Control (n=575) N (%)	Crude OR (95% CI) p value	Adjusted OR (95% CI) p value
Physical (primary)	113 (21%)	117 (20%)	1.1 (0.75 to 1.36) 0.934	0.98 (0.72 to 1.33) 0.892
Sexual (primary)	109 (20%)	121 (21%)	0.93 (0.69 to 1.26) 0.648	0.98 (0.72 to 1.32) 0.881
Emotional	216 (39%)	259 (45%)	0.79 (0.61 to 1.03) 0.079	0.74 (0.56 to 0.98) 0.035
	n=170	n=177		
Disclosed IPV in past year (among those experiencing physical/sexual IPV in past year)	118 (69%)	135 (76%)	0.71 (0.44 to 1.14) 0.151	0.75 (0.46 to 1.21) 0.239
Attitude/belief	(n=551)	(n=575)		
Attitudes accepting of IPV	282 (51%)	373 (65%)	0.56 (0.42 to 0.74) <0.001	0.49 (0.36 to 0.66) <0.001
Believes a woman should tolerate violence in order to keep her family together	82 (15%)	148 (26%)	0.50 (0.37 to 0.69) <0.001	0.48 (0.34 to 0.66) <0.001
Believes IPV is a private matter and others should not intervene	58 (11%)	100 (17%)	0.56 (0.39 to 0.81) 0.002	0.54 (0.38 to 0.78) 0.001

*One woman reported never being partnered so excluded from the analysis. IPV, intimate partner violence.

Table 3B Intervention impacts on primary and secondary outcomes among those attending seven or more intervention sessions, compared with controls matched on propensity for high intervention attendance*

Type of intimate partner violence/abuse	Intervention (n=464) N (%)	Control (n=464) N (%)	Crude OR† (95% CI) P value	Adjusted OR‡ (95% CI) P value
Physical	95 (20%)	98 (21%)	0.96 (0.70 to 1.32) 0.808	0.96 (0.69 to 1.34) 0.812
Sexual	91 (20%)	98 (21%)	0.92 (0.65 to 1.29) 0.616	0.97 (0.70 to 1.36) 0.873
Emotional	171 (37%)	214 (46%)	0.68 (0.51 to 0.90) 0.008	0.65 (0.48 to 0.87) 0.004
Disclosed violence in past year (among those experiencing physical/sexual IPV in past year)	99/142 (70%)	109/145 (75%)	0.76 (0.45 to 1.29) 0.305	0.80 (0.47 to 1.38) 0.425
Attitude/belief				
Attitudes accepting of IPV	235 (51%)	296 (64%)	0.57 (0.42 to 0.78) <0.001	0.51 (0.37 to 0.71) <0.001
Believes a woman should tolerate violence in order to keep her family together	69 (15%)	123 (27%)	0.48 (0.34 to 0.69) <0.001	0.47 (0.33 to 0.67) <0.001
Believes IPV is a private matter and others should not intervene	48 (10%)	84 (18%)	0.52 (0.35 to 0.78) 0.001	0.52 (0.35 to 0.77) 0.001

*Propensity score predicted based on a logistic regression model fitted to women in the intervention arm, with 7+ sessions as the dependent variable and independent variables comprising baseline measures of cluster size, age, religion, marital status, highest level of education attended, number of children, experience of sexual and/or physical IPV (never/ ever but not past yr/ past year), past year experience of controlling behaviour, and poor mental health.

†Crude OR point and interval estimates and p value are from a logistic regression with cluster-level random intercepts but no adjustment for baseline covariates.

‡Adjusted OR point and interval estimates and p-value are from a logistic regression with cluster-level random intercepts and adjustment for baseline measure of outcome (Y/N/NA), secondary or higher education (Y/N) and age (linear).

IPV, intimate partner violence.

IPV was reduced by around a third.¹² There are several potential reasons for these contrasting findings.

First, important differences in the underlying risk factors for IPV of the two trial populations could explain

the different intervention effects observed. Women (and their partners) in the current trial were on average younger than those in the previous trial (women's mean age at baseline 33.1 years, (SD 8.1 years) vs 39.6 years,

(9.5 years)), and reported higher levels of past year physical and/or sexual IPV at baseline (35% vs 26%). Another key difference between the two populations is level of education, which is well-recognised as a risk factor for IPV.¹⁹ Overall, participants in the current trial were less educated with 19% having received no education or incomplete primary education compared with 14% of CRT01 participants.¹² Having less formal education does not seem to have impacted on women's participation in the intervention; the facilitators reported that women were very engaged and interactive during the sessions. However, they may have faced more challenges in implementing changes at home to reduce violence.

Second, participants in the previous trial were recruited and participated in the MAISHA intervention in their pre-established microfinance groups. It is likely, therefore, that they had already developed strong social ties with their fellow group members. Evidence suggests that social capital, such as that gained through group membership, may provide women with some forms of protection, as well as the confidence to address physical IPV.²⁰ It is possible that this support combined with a slightly higher level of formal education, meant that these women were already further along a trajectory of empowerment at the outset of the trial, that is, thinking about and challenging social norms that promote gender inequalities.²¹ Conversely, for the current trial, women living in the same neighbourhood were formed into groups specifically for the purpose of the intervention, and may not have had pre-existing social ties with other group members. Perhaps these women needed more time to bond as a group and develop social trust and solidarity before participating in the MAISHA intervention. Even so, we are aware that there were tensions within some of the microfinance groups over the collective responsibility for individual debt, which sometimes impacted negatively on group cohesiveness.

Third, in addition to being less educated than women in the previous trial, other indicators suggest that women in the current trial experienced greater levels of poverty. They were more likely to report household economic hardship, as measured by difficulty in covering basic household needs such as food and medicine (62% vs 47%). The relationship between poverty and women's experience of IPV is complex and the evidence suggests multiple ways in which poverty drives IPV both directly and indirectly.¹⁹ Indirectly, growing up in poverty increases the likelihood of experiencing recognised risk factors for IPV, including poorer educational outcomes, and adverse childhood experiences such as physical, sexual and emotional abuse, and neglect.^{22 23} More directly, high levels of stress in households struggling to manage scarce resources, can lead to conflict and violence.^{24 25} A number of studies have demonstrated associations between food insecurity (an indicator of acute poverty) and women's experience of IPV.^{19 23 26} Any effects of the MAISHA intervention may not have been sufficient to counteract these additional stressors present in the current trial.

Fourth, as well as overall levels of household poverty, women's lack of access to and control over economic

resources is also a driver of IPV risk, limiting women's power within relationships as well as their ability to leave abusive relationships. Women in the current trial were not participating in formal microfinance, were less likely than those in the previous trial to report personally earning money (80% vs 97%), and where they did so their income was lower (median of 110 000 vs 220 000 Tanzanian shillings per month). Starting from a point of greater financial independence from their male partners, the MAISHA intervention may have enabled women in the previous trial to enact change within their relationships. For women in the current trial, however, greater economic dependence on male partners might have limited the extent to which they were able to translate changes in personal 'empowerment' into relationship-level change.

Given the ways in which poverty increases women's vulnerability to IPV, there has been considerable research focused on economic interventions to prevent women's experience of IPV.⁷ Much of the research addresses whether economic interventions alone are sufficient to reduce IPV, or whether they should be delivered in combination with social empowerment or gender transformative interventions. The evidence indicates that programmes combining economic strengthening with social empowerment for women tend to lead to positive outcomes,^{7 27} with cash transfer interventions more consistently linked to reductions in IPV than microfinance interventions for which the evidence is more mixed.²⁸ The related but conceptually opposite question of whether social empowerment interventions alone can work in the absence of economic interventions, has received less attention. This trial suggests that a social empowerment intervention alone for women is not sufficient to reduce IPV. However, we cannot comment on whether these results can be generalised to other women in Tanzania. For example, women in higher socioeconomic groups.

It is possible that we might have seen an intervention effect on physical and sexual violence if male partners had also participated in the intervention, as originally planned. There is good evidence that couples' interventions, which are well designed and well implemented, are effective in reducing IPV against women.⁷ Such interventions require careful consideration of the population being targeted, including understanding how masculinities operate and are related to IPV perpetration in specific contexts.²⁶

The MAISHA intervention had a considerable impact on women's attitudes and beliefs about violence. Although we cannot exclude the possibility of social desirability bias, it is worth noting anecdotal evidence from the field team suggesting that women seemed more confident about challenging violence in their communities.

Similar to the previous MAISHA trial and other trials,¹⁵ there was no effect on sexual IPV in this trial. We did not assess women's acceptance of sexual IPV, however, social norms supporting sexual entitlement of men are deeply entrenched in Tanzania. The lack of impact on sexual IPV in both MAISHA trials indicates the need to engage more with men. Although they did not refer to sexual IPV explicitly,

the trial participants highlighted the need to include men in violence prevention interventions.

In contrast to the previous trial there was a reduction in reports of emotional abuse by intervention arm women compared with control arm women. This is an encouraging finding given the link between mental ill health and emotional abuse.²⁹ The overall prevalence of emotional abuse was high in both MAISHA trial populations; however, it is not clear why there was an impact of the intervention on this form of abuse in the current trial but not in the previous trial. Secondary analyses are underway to explore potential explanations for the different intervention effects in the two trials, alongside questions of how mechanisms of change may have differed in the two trials. These exploratory analyses augmented by rich data from the longitudinal qualitative study of a subsample of trial participants,²¹ will provide valuable insights into these results, and provide an opportunity to better understand the potential for the MAISHA intervention to be transferred and adapted to other settings.

We observed a slightly stronger effect on emotional abuse when we restricted the analysis to women who attended seven or more sessions; however, we did not observe any strengthened impact on other outcomes in this 'high-dose' group. This is perhaps unsurprising given the high attendance at sessions, which of itself is encouraging and suggests the MAISHA intervention is acceptable to women.

There are some limitations. Women who participated in the trial are among the poorest in Mwanza city, and the results are possibly not generalisable to women who are more economically advantaged. Reporting bias is a concern, particularly as under-reporting of IPV is common. It is possible that exposure to the intervention might have increased sensitisation of women to IPV leading to increased reports of violence among women in the intervention arm, and thereby an underestimate of the effect size. Given the nature of the intervention, 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 research¹¹ with face-to-face interviews conducted by interviewers who had received extensive training and had not been involved in implementation of the intervention.

The trial has many strengths. Randomisation of groups ensured that there was no bias in programme placement. Women were enrolled from a large number of neighbourhoods across Mwanza city ensuring that the trial was adequately powered. Engagement with the intervention was very good and most participants attended at least seven of the 10 sessions, suggesting that the intervention is acceptable to women. Retention rates were high for both arms (88% intervention arm vs 90% control). Although it is possible that the women lost to follow-up differed from those included in the analysis, baseline comparisons with the ITT population do not support this suggestion. Furthermore, the impact of the intervention remained much the same when those lost to follow-up were included in the outcomes analysis using multiple imputation. Data were analysed following the ITT principle and a pre-specified analysis plan, with data analysts

blinded to trial allocation. Baseline data enabled us to adjust for baseline imbalances between the trial arms (according to the pre-specified analysis plan). The mixed-methods design of the trial, utilising quantitative and qualitative approaches, will allow us to gain 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, processes of change, and potential reasons for its impact or lack of impact on different forms of violence and abuse.

In summary, IPV is a major problem globally. This trial is an important addition to the body of evidence on what works to prevent violence.^{6,7} It has shown that although this gender transformative intervention did have a considerable impact on attitudes and beliefs about violence, and on emotional abuse experienced by women, it was not sufficient to reduce physical or sexual IPV. Current evidence indicates positive outcomes when social empowerment or gender transformative interventions are combined with economic strengthening for women.^{7,27} However, it is also crucial to engage men in strategies to prevent all forms of violence against women, and there is accumulating evidence that couples' interventions, focussing on transforming gender relations within the couple, are also effective in reducing women's experiences of IPV.⁷

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Contributors SH provided methodological input, coordinated the trial and managed the trial teams with assistance from IK, and wrote the first draft of the trial report. TA did the statistical analysis and cowrote the first draft of the trial report. GM contributed to the trial design and provided methodological input into the qualitative study. CHH provided methodological input and statistical support. GJM and FM led the field team responsible for recruitment of participants and data collection. RH set up and managed the data management systems. CW conceived the idea and design of the trial and provided methodological input. SL contributed to the trial design and provided methodological input and oversight of the qualitative study. SK contributed to the trial design, provided methodological input and oversight of the trial. All authors contributed to interpreting the data and writing the manuscript.

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Competing interests Following initiation of the trial, CW was 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 LSHTM.

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